Is guided self-help a treatment option for people with intellectual disability?

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IS GUIDED SELF-HELP A TREATMENT OPTION FOR PEOPLE WITH INTELLECTUAL DISABILITY?

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Doctor of Philosophy (PhD) Thesis

December 2013

ABSTRACT

Introduction

There is little evidence of the use of guided self-help as an intervention for people with intellectual disability. The **S**elf-**A**ssessment and **INT**ervention, is a guided self-help tool designed specifically for this group. There are three linked studies within this thesis that aim to; [1] develop a guided self help intervention [2] test its reliability and validity and [3] pilot it in practice using a single case experimental design.

Method

The SAINT was developed using Delphi methodology and focus groups and has demonstrated good reliability and validity. The pilot was conducted in two parts; part 1 had 15 recruits to test the intervention, whilst part 2 (which aimed to replicate the findings over an extended period) had three recruits, including two from part 1. A Nurse visited each participant weekly to facilitate the intervention.

Results

Reliability testing was completed on 59 participants. The SAINT showed significant correlation at the p <0.001 levels, (2-tailed) with the GDS-LD (r = 0.619), GAS-ID (Worries) (r = 0.496), with test-retest correlation (N=25), 0.881 at the p < 0.01 level (2-tailed) and a Cronbach Alpha score of = 0.828 suggesting good internal consistency and reliability. From part 1 twelve out of fifteen people completed the intervention, of these nine (75%) demonstrated a decreased symptom scores in both, of the intervention phases for depression and three (25%) for anxiety. In part 2, both participants from part one replicated positive results; as did the new participant. For all cases anxiety improved in both intervention phases N=3 (100%), as did depression in n=2, (66.6%). Those with a history of affective disorders (n=8) showed the most consistent improvement.

Summary

The SAINT has shown itself as a potentially viable and valid treatment option. It has shown a decrease in mean symptom scores for the majority of participants; which more importantly were replicated over an extended period in part 2 of the pilot for two participants.

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ACKNOWLEDGEMENTS

I would firstly like to show appreciation to my first supervisor Professor Tom Craig for his patience, advice and challenging me to become a better researcher. Secondly my second supervisor Professor Nick Bouras, who had the faith and confidence to put me forward for this opportunity and who has also supported me throughout.

This is an unfunded project, however a number of people have made themselves available to me at different times over the last 6 years to offer their advice, support and to promote this work. These include Rebecca Chester, Steve Hardy, Michael Fullerton, Lisa Underwood and Dr. Jane McCarthy.

I would also like to thank all those people I was lucky enough to meet and who gave their time to take part in the study. My final thoughts are for those participants who sadly are no longer with us.

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CONFERENCE PRESENTATIONS

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Eddie Chaplin (2013) SAINT: A guided self-help tool for people with intellectual disability IASSIDD. Asia-Pacific Regional Congress, 22nd August 2013, Tokyo, Japan. Poster.

Developing a guided self help pack for people with intellectual disabilities: Workshop, 8th European Association for Mental Health in Intellectual Disabilities Annual Conference (MHID 2011) Sep 01, 2011 - Sep 03, 2011: Palace Hotel, Manchester, England, United Kingdom. Workshop

Piloting a guided self help pack called the SAINT for adults with Intellectual Disabilities: PhD Research Showcase Event; 18th November 2011: Institute of Psychiatry Kings College London. Poster.

ABBREVIATIONS

ASD	Autism Spectrum Disorders
BAI	Beck Anxiety Inventory
BDI	Beck Depression Inventory
BPRS	Brief Psychiatric Rating Scale
CANDID	Camberwell Assessment of Need for Adults with Developmental and Intellectual Disabilities
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CB	Challenging Behaviour
CBT	Cognitive Behavioural Therapy
CD	Compact Disc
CE	Clinical Expert
CI	Confidence Intervals
CPN	Community Psychiatric Nurse
CWD	Coping with Depression
df	Degrees of Freedom
DV	Discriminant Validity
ECT	Electroconvulsive Therapy
Embase	Excerpta Medica Database
FA	Factor Analysis
FrA	Framework analysis
GHQ	General Health Questionnaire

GAS-ID	Glasgow Anxiety Scale for people with Intellectual Disability
GDS-LD	Glasgow Depression Scale for people with Learning Disabilities
G.P	General Practitioner
GSH	Guided Self-Help
H	Hypothesis
HADS	Hospital Anxiety and Depression Scale
HAMD	Hamilton Depression Rating Scale
IAPT	Improving Access to Psychological Therapies
ICD-10	International Classification of Diseases (10th revision)
ID	Intellectual Disability
IOA	Inter Observer Agreement
K	Number of Studies
KMO	Kaiser-Meyer-Olkin
LD	Learning Disability
M	Mean
MDD	Major Depressive Disorder
MRC	Medical Research Council
N	Number in Population
n	Number in Sub Population
n.s	Not Significant
NCCMH	National Collaborating Centre for Mental Health
NHS	National Health Service
NICE	National Clinical institute for Clinical Excellence

NIHR	National Institute of Health Research
PI	Principal Investigator
PICO	Patient, Intervention, Comparison and Outcome
Psych Books	A full-text database of books and chapters in the APA's electronic databases
Psych Extra	A grey literature database, which is a companion to PsycINFO
PsycINFO	Psychological Information Database
PASS-ADD	Psychiatric Assessments Schedules for Adults with Developmental Disabilities
SAINT	**S**elf-**A**ssessment and **INT**ervention
SCED	Single Case Experimental Design
SD	Standard Deviation
SMD	Standardised Mean Difference
SOTSEC-ID	Sex Offender Treatment Services Collaborative – Intellectual Disabilities
SUE	Service User Expert
RCT	Randomised Controlled Trial
RR	Relative Risk/Risk Ratio
TAU	Treatment as Usual

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CHAPTER 1 INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

This thesis describes a developmental research project to construct and pilot a guided self-help (GSH) tool specifically for people with intellectual disability, known as the **S**elf-**A**ssessment and **INT**ervention (SAINT). The thesis is formed of three linked studies that aim to establish proof of concept (i.e., that people with intellectual disability can use and benefit from GSH approaches) and to establish the characteristics of people within intellectual disability populations who may benefit from GSH in order to inform any future more definitive investigation such as a Randomised Controlled Trials (RCT) (see Lancaster, Dodd & Williamson, 2004).

The three studies are:

1. The development of the SAINT as a GSH intervention for people with intellectual disability
2. Testing the reliability and validity of the SAINT
3. A pilot study to establish the feasibility, acceptability and likely effectiveness of the SAINT

GSH approaches are fast becoming an important tool in the repertoire of interventions for the management of common mental health problems (National Collaborating Centre for Mental Health, 2010) but the development of these approaches in the field of intellectual disability face a number of challenges, not least the difficulty of establishing mental health diagnoses in this population. The

study of the mental health needs of people with intellectual disability has only gained momentum in the last 50 or so years, and has led to an increased recognition, awareness and acceptance of mental illness in people with intellectual disability (Hemmings, Deb, Chaplin*, et al*, 2013) with rates estimated between 20.1% -22.41% (excluding challenging behavior (CB)) (Cooper, Smiley, Morrison*, et al*, 2007). This compares to a rate of 16% in the wider general population (Department of Health, 2003).

People with intellectual disability form a heterogeneous population. The assessment and treatment of mental illness for this group may be more complex than in the general population for a number of reasons. These include; difficulty in comprehension, language, expression and conceptualisation (Lunsky & Palucka, 2004). Often concepts described within diagnostic interviews are complex and an inability to express emotions and describe experiences in an ordered fashion can affect accurate diagnostic formulation. For some people a good vocabulary may give a false impression as to their level of understanding, and as a result their abilities can be overestimated. It is also the case that poor verbal articulation may mean that the person's level of ability is underestimated. An inability to express oneself or lack of awareness of the significance of symptoms may mean that symptoms such as guilt, low self-esteem, self worth, negative and rumination are less likely to be forthcoming. In the assessment of mental disorder in people with intellectual disability, in particular those who are poor reporters or personal historians, there is an extra reliance on reports from others to corroborate evidence and provide observation of physiological markers (sleep, diet etc.).

The awareness of the needs of people with intellectual disability for clinicians is vital. How questions are phrased will have a bearing on the response, for example

leading questions are a bad idea and those requiring only a yes/no response will be problematic for those who acquiesce. The inability to express or understand symptoms adequately may contribute to an atypical presentation. Smiley and Cooper (2003) examined a range of studies and found similar behaviour patterns (e.g., aggression) in individuals diagnosed with depression that were not typical of a diagnosis in non-intellectual disability populations. The questions of whether symptoms such as aggression, irritability and other expressions of CB, are a sign of mental disorder (known as behavioural equivalents) or are they in fact a natural reaction by the individual to their circumstances is not new. Psychiatric morbidity among people with intellectual disability is associated with higher levels of CB (e.g., (Bouras, Kon & Drummond, 1993; Felce, Kerr & Hastings, 2009; Hemmings, Deb, Chaplin*, et al*, 2013). The notion that symptoms have behavioural equivalents is disputed and a more apt term may be behavioural correlates i.e., the behaviour coexists with mental health problems, rather than being an indication of it (Hemmings, Deb, Chaplin*, et al*, 2013). The dilemma when conducting assessments is whether these behaviours should be incorporated within diagnostic schedules or not. The argument centres on whether symptoms such as aggression, irritability and other expressions of CB, are a sign of other mental disorder or are in fact a natural reaction by the individual to their circumstances. The additional challenges of making a mental health diagnosis in people with intellectual disability has led to the questioning of the validity of standard classification systems used to diagnose mental illness in this group. As a result there are now intellectual disability versions of the International Classification of Diseases, 10th edition (World Health Organisation, 1992) and the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision (American Psychiatric Association, 2000) diagnostic manuals, with an

update for DSM-V in preparation. This is part of an ongoing trend that has seen a number of measures specific to intellectual disability populations being developed which has coincided with the belief that available diagnostic manuals and clinical measures may not be suited to those individuals who have difficulty in comprehension, language, expression and conceptualising (Lunsky & Palucka, 2004).

Mental health care for people with intellectual disability should be consistent with that of the wider general population; however in reality there is difficulty for many accessing mental health services and those that do may be less likely to receive psychological treatments (Michaels, 2008). The availability of psychological interventions for people with intellectual disability have grown as the understanding of the mental health needs of this group has increased (Hatton, 2002). This growth has made a wider range of less intrusive person centered treatment options available and as helped to dispel the myth that this type of approach is unsuitable for people with intellectual disability. However access to this type of treatment is variable across the UK. Currently there is an over reliance on prescribing of medication for mental illness for people within intellectual disability. This practice should be in line with the National Clinical institute for Clinical Excellence (NICE) guidance; however there are estimates of between 20-90% of people with intellectual disability have been prescribed psychotropic medications as a result of antisocial or CB. (Hemmings, Deb, Chaplin*, et al*, 2013). Unfortunately once the person comes to the attention of services it is more likely they will receive psychotropic medications in the absence of any identifiable mental illness. In England specialist mental health service models for people with intellectual disability differ across the country. Although current policy is that people with intellectual disability access mental

health services in the same way as everyone else, there is still considered a need to provide specialist services for the most complex cases.

Within the UK two specialist mental health service models have been described, although neither has been formally evaluated. These are 1) - the Mental Health Service for People with Learning Disabilities (MHSPLD). This is an integrated model provided on an acute mental health ward staffed by mental health nurses with additional input from intellectual disability clinicians and has reported shorter lengths of stay compared to inpatient service models (Hall, Parkes, Samuels*, et al*, 2006). The second is the 2) – Mental Health in Learning Disabilities model (MHiLD) (Bouras, Cowley, Holt*, et al*, 2003; Bouras & Holt, 2001; Chaplin & O'Hara, 2008). The service offers specialist mental health provision as a discrete entity and interfaces with local mental health services and benefits from an integrated training and research centre. The service comprises outpatient clinics and a small specialist inpatient assessment and treatment unit.

Anxiety and depression even at low levels of severity are associated with increased risk of mortality (Russ, Stamatakis, Hamer*, et al*, 2012); and in spite of the higher risks of mental health problems in people with intellectual disability (Cooper, 2006; Cooper, Smiley, Morrison*, et al*, 2007; Cooper, McConnachie, Allan*, et al*, 2011; Smiley, Cooper, Finlayson*, et al*, 2007; Whitaker & Read, 2006), there is little in terms of self-help materials outside the context of individual psychological therapy to address this. There is no evidence to suggest people with intellectual disability use the GSH packages currently available. This is for a number for reasons including:

- Cognitive impairment, which may mean the person has difficulty understanding the concept of GSH and may need additional support to use the approach
- A lack of opportunity and flexibility in the person's life to enjoy activities that enhance mental wellbeing as and when they choose e.g., activities with a strong educational component or financial cost to the individual
- The mode of delivery of the intervention e.g., internet programmes, which may not be accessible or easily accessed
- Expectations of the programme, e.g., the need to adhere to agreement or contracts

The barriers to accessing GSH can also affect parts of the wider community with specific learning difficulties, such as dyslexia or those who are unable to read or write. This is an issue in western society e.g., in the United States of America, from a sample of 26,901 (representing a total population of 191,289,000); 22% of the population function as illiterate and 44% will not have read a book (Kirsch, Jungeblut, Jenkins*, et al*, 2002). This compares to 16%, (5.2M) in the UK, who have a reading level below that expected of an 11 year old (Department for Education and Skills, 2003).

The need to develop specialist GSH measures has recently been identified by the National Institute for Clinical Excellence Autism Guidelines (2012) as a research priority. This is important in the context of this study with autism estimated to be present in 20-34% of adults with intellectual disability (Emerson & Baines, 2011).

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1.2 **Literature review**

The difficulty of obtaining comprehensive search information from electronic databases is well recognised (Doel, Carroll, Chambers*, et al*, 2007). In intellectual disability research a lack of common vocabulary relating to definition and terminology both nationally and internationally are examples to illustrate this.

This literature review aims to provide a synthesis of available research and to critically evaluate the quality of evidence relating to efficacy of GSH, its adaptation and translation to clinical practice for people with intellectual disability.

1.3 **Search**

The search strategy incorporated a PICO framework (patient, intervention, comparison and outcome) to plan and structure and organise concepts and terms to search the identified databases. Patients were identified by a diagnosis of intellectual disability and its variant terms. The intervention "guided self help" was not compared to any alternative treatments so the comparison section in this instance was not applicable. The effectiveness of outcomes related to depression and positive mental wellbeing. The PICO structure and strategy is shown below in Figure 1.The search strategy uses Boolean logic. This allows search terms to be combined or excluded using the Boolean operators i.e., AND, OR and NOT. The use of wildcards was used to address differences in spelling e.g., behavior – behavior and truncation symbols are used for keywords. This is useful for finding singular/plural forms of words and also variant endings.

Patient	Intervention	Comparison	Outcomes
Intellectual Disability	Guided Self Help	N/A	Mental health improvement
Intellectual disorder Learning disorder Learning disability Mental retardation Mental handicap Mental Impairment	Self help Self intervention Self monitoring Self treatment Self assessment		Mental health outcomes Mental wellbeing Depression Anxiety

Figure 1 PICO Search strategy

The primary search was conducted through the Ovid database, from which the following databases were searched; Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present, Ovid OLDMEDLINE(R) 1946 to 1965, PsycINFO 1806 to October Week 1 2013, Your Journals@Ovid, Books@Ovid October 03, 2013, PsycARTICLES Full Text, Global Health 1973 to 2013 Week 39, British Nursing Index and British Nursing Index Archive. This was supplemented by regular contents appraisal of peer review journals written in English, specialising in intellectual disability and/or intellectual disability psychiatry and covered parts of Europe, North America, Australasia and Hong Kong. The search also included new journals yet to receive an impact factor and grey literature searches using internet search engines such as Google, Yahoo and Bing.

The original search in 2007 returned 7 articles, none of which were suitable for review because they did not relate to intellectual disability. This has been updated through the course of the study; with the latest search (7th October 2013) identifying 22 articles see Figure 2

1	((intellectual: or learning) adj3 (disab: or disorder: or handicap:)).mp.	235226
2	(mental: adj3 (retard: or handicap: or deficien:)).mp.	235511
3	mental impairment.mp. [mp=ao, ab, ec, ei, fa, fc, fi, fm, hw, ie, lc, oi, sa, si, sm, ti, ot, rw, nm, tn, kf, ps, rs, an, ui, tc, id, tm, tx, sh, ct, bt, de, dm, mf, dv, kw, pt]	5989
4	or/1-3	402860
5	(self: adj3 (monitor: or help: or intervention:or assessment: or treatment:)).mp.	185237
6	guided self help.mp. [mp=ao, ab, ec, ei, fa, fc, fi, fm, hw, ie, lc, oi, sa, si, sm, ti, ot, rw, nm, tn, kf, ps, rs, an, ui, tc, id, tm, tx, sh, ct, bt, de, dm, mf, dv, kw, pt]	1113
7	(or/5-6) and 4	6700
8	4 and 6	28
9	(mental: adj3 (health: or health outcomes: or wellbeing:)).mp.	816761
10	Depress:.mp.	1856499
11	Anxiety:.mp.	873872
12	or/9-11	2883037
13	8 and 12	25
14	remove duplicates from 13	22

Figure 2 Search strategy

Of the 22 papers recovered, only three related to GSH and intellectual disability, all of which were related to this current thesis (Chaplin, Chester, Tsakanikos*, et al*, 2013; Chaplin, Craig & Bouras, 2012) with one duplicate.

1.4 **Issues in accessing healthcare**

It is well recognised that people with intellectual disability suffer higher health inequalities with poorer outcomes (Michaels, 2008), which is evidenced by increased morbidity and mortality rates (Emerson & Baines, 2010; Kerr, Felce & Felce, 2005.; McCarthy & O'Hara, 2011; McGuigan, Hollins & Attard, 1995; Patja, 2000)

compared to the general population estimates. Contributing factors include poor access to health care, and limited communication skills which may reduce the person's ability to convey their health needs effectively to others (Emerson & Baines, 2010). The difficulties and lack of equity experienced by people with intellectual disability trying to access health care and its consequences is well documented (Disability Rights Commission, 2006). This issue has been increasingly highlighted within the media following the disturbing 'Death by Indifference' reports (Mencap, 2007; Mencap, 2012) and the subsequent inquiry to the 2007 report 'Healthcare for all' (Michaels, 2008). Within mental health settings there are also major gaps in provision characterised by inconsistent models of care and care pathways (Bouras, 2004; Chaplin, O'Hara, Holt*, et al*, 2009; Department of Health, 2001b; Royal College of Psychiatrists, 2003), in particular access to secondary tier services and psychological interventions (Cooper, McConnachie, Allan*, et al*, 2011).

1.5 Prevalence of intellectual disability and mental health

The prevalence of people with moderate and mild intellectual disability is estimated at 25 per 1000 of the population, which equates to 1.2 million people in England (Department of Health, 2001b). Recent epidemiological studies of mental health problems within this group put prevalence rates of mental disorder at just over 20% (Cooper, Smiley, Morrison*, et al*, 2007) compared to 16% in the wider population (Department of Health, 2003). The lifetime prevalence of depression in people with intellectual disability is estimated to be 16.2%, (Kessler, 2003) with a point prevalence of 3–4% (Smiley, 2005), compared to rates of between 1.7% found in the general population (Kessler, 2003; and a point prevalence of between 2.2 - 2.8 over

the last 20 years for depression among adults Meltzer, Brugha, Bebbington*, et al*, 2007). Anxiety related disorders are reported at a higher rate in people with intellectual disability; generalised anxiety disorder 6%, specific phobia 6%, agoraphobia 1.5% and obsessive compulsive disorder 2.5% (Smiley, 2005), compared to the general population who are estimated to have a 28.8% lifetime prevalence rate (Kessler & Wang, 2008). These estimates do not take into account those with sub threshold symptoms who are often excluded from psychological treatments and other mental health care. This can be for a number of reasons including; not meeting current eligibility criteria, a false perception of the ability of people with intellectual disability to engage, or because therapies have not been adapted for use for people with intellectual disability. The available evidence suggests that not only does the presence of sub threshold symptoms indicate a greater risk to later depressive episodes, but that they can also independently predict future episodes of depression and anxiety. The best predictors of depression are a history of both clinical and sub threshold symptoms followed by the presence of either clinical or sub threshold symptoms. Anxiety and depression are related in terms of their co existence through high co morbidity. For people with intellectual disability the presentation of anxiety and/or depression may be atypical or masked because of communication difficulties, identifying and knowing relevance of symptoms, and poverty of experience may also mean the significance of events to the person might be missed and how the experience impacts upon them.

The clinical challenges posed by people with intellectual disability and mental health problems are gaining wider recognition although further support and greater awareness is required to ensure that this group of people with complex needs benefit from the full range of mental health services, from primary care to specialist mental

health provision and to address the current lack of expertise and capacity. This also applies to involvement with research, which should be a priority according to the Sainsbury Centre for Mental Health, (Samele, Wallcraft, Naylor*, et al*, 2007).

1.6 Economic Costs of poor Mental Health

In the general population mental ill health has a major impact on the health economy; the direct cost of depression alone is estimated at £370m (Thomas & Morris, 2003). It is estimated that there are 1.24 million people with depression in England. This is projected to rise by 17% to 1.45 million by 2026 (McCrone, Dhanasiri, Patel*, et al*, 2008). The burden of depression on society is wide ranging and is responsible for, reduced productivity and increased sickness with state support estimated at between £7.5 and £8 billion. The average cost of GSH in 2007/08 was estimated to range from £42 to £259 per person (Lovell & Richards, 2008). In the short term GSH may be more costly than anti-depressants however any comparison is difficult with GSH indicated in milder forms of depression, often prior to pharmacological intervention. This is not to say those with more severe symptoms or major depression cannot use it in combination with anti-depressants. There is however little in the way of evidence on the impact of mental illness (including depression and anxiety) to the lives of people with intellectual disability in terms of life opportunities and cost. Therefore, overall treatment costs are difficult to estimate as treatments and services that are available vary.

1.7 **Guided Self Help**

The NICE Guidelines (GG90) (National Collaborating Centre for Mental Health, 2010, p182) define GSH as,

"… a self-administered intervention designed to treat depression, which makes use of a range of books or other self-help manuals derived from an evidence-based intervention and designed specifically for the purpose. A healthcare professional (or paraprofessional, for example, graduate and low-intensity workers in mental health) facilitates the use of this material by introducing, monitoring and reviewing the outcome of such treatment. This intervention would have no other therapeutic goal and would be limited in nature, usually to no less than three contacts and no more than six". This equates to no more than 3 hours of input, which is considered half the minimum time required for conventional psychological therapy, (Gellatly, Bower, Hennessy*, et al*, 2007).

GSH is not to be confused with self-help, which is geared towards supplying information. GSH is the second stage and part of the stepped-care approach of interventions for depression (see **Error! Reference source not found.**). The stepped care provides a hierarchy of treatment options according to the severity of clinical presentation, whilst considering the aim and focus of any intervention according to the person's needs (Bower & Gilbody, 2005).

	Who is responsible for care?	What is the focus?	What do they do?
Step 5	In patient and crisis teams	Risk to life Severe self neglect	Medication, combined treatments ECT. Increased level of observation
Step 4	Mental health specialist and Crisis teams	Recurrent, atypical and those at significant risk	Medication, combined treatments ECT
Step 3	Primary care team & Primary care mental health	Moderate or severe mental health problems	Medication, combined treatments Complex psychological interventions
Step 2	Primary care team & Primary care mental health	Mild mental health problem	Watchful waiting **Guided Self Help**, Brief Psychological therapy, Computerised CBT, exercise
Step 1	GP Practice Nurse	Recognition	Assessment

Figure 3 The stepped care approach

The use of low-intensity interventions such as GSH that promote positive mental health, mean that many people do not need or go on to receive more intrusive treatments, that may produce unwanted side effects and that are less well tolerated. GSH allows the involvement of others who are important to the person and who would support them either formally or informally in line with Recovery principles (Lovell & Richards, 2008). GSH allows the individual to manage their own symptoms where possible and ultimately aims to reduce dependence by transferring control (Lovell, Bower, Richards*, et al*, 2008). For ease of use there have been attempts to standardise the implementation of GSH within the United Kingdom, although there is as yet no consensus e.g., the NICE guidelines recommendations have taken the opportunity to advocate for more accessible materials to support access to GSH, and identified four distinct methods to deliver GSH; frequent support, minimum support, group psychoeducation and support by mail. This is in contrast to the four levels identified by the Scottish Executive (2006): information on

common mental health problems, advice and coping, self-directed structured plan, supported self-help.

According to NICE guidelines, individual GSH programmes based on the principles of Cognitive Behavioural Therapy (CBT)[1] should:

- Include the provision of written materials of an appropriate reading age (or alternative media to support access)
- Be supported by a trained practitioner, who typically facilitates the self-help programme and reviews progress and outcome
- Consist of up to six to eight sessions (face-to-face and via telephone) normally taking place over 9 to 12 weeks, including follow-up.

(National Collaborating Centre for Mental Health, 2010, pp., 13-214).

1.8 Evidence for GSH as an effective Mental Health Intervention

Research into GSH in intellectual disability is poor. There was no evidence found during the search of RCTs, systematic reviews, outcome or case studies, with the only evidence found of GSH for people with intellectual disability was an unpublished study outside of the main search strategy. This was a funded one-year pilot study located in Scotland, which was unable to reach any reasonable conclusions due to recruitment difficulties and attrition (Davidson, 2010, *personal communication*). The intervention comprised of five short plain language pictorial booklets based on CBT principles for self-help and low mood. The booklets covered:

[1] This includes behavioural activation and problem-solving techniques for people with persistent sub threshold depressive symptoms or mild to moderate depression.

1. Feeling down and related symptoms/behaviours
2. Doing more positive daily activities to help improve mood
3. Addressing poor sleep patterns
4. Being more physically active
5. An educational booklet aimed at the carers

Participants were asked to use the GSH booklets over a 12-week period, and be supported by carers if required and where possible. Recruitment to the pilot, was described as satisfactory, however keeping people in treatment was the main problem encountered. This was thought to be for a number of reasons including: staff commitment, carers going on long term sick, staff competence to deliver the intervention. With a strong emphasis on support a number of support staff expressed that they felt concerned as to whether they were providing the right kind of 'advice' to people when addressing particular issues. Some also felt that it was not their job, seeing it as more the role of a psychologist/external agency or that they weren't supported by management to spend the time doing it (Davidson, 2010) *personal communication*.

There are a number of publications that have reported case studies and case series to describe the use of self-assessment and/or intervention techniques for people with intellectual disability. These studies have predominantly included offenders or those described as “at risk of offending”, and have focused on self-management in the context of individual prescribed care packages. The techniques and strategies employed within these studies have included diaries, self-monitoring and relaxation exercises, which are completed as homework, following individual or group

sessions. These studies have demonstrated that people with intellectual disability are able to use and benefit from self help techniques central to GSH. Taylor (2002) reported twelve studies (1986–2002) the majority of which focused upon skills training within a cognitive behavioural framework. This included self-instruction and interpersonal problem solving aimed at addressing cognitive deficits, rather than to modify cognitive content and distortions. The dependent variables varied throughout these studies and included anger, aggression, provocation inventories, self-esteem, depression and role-play. Ten of the studies were followed up over varying time periods of between four weeks to twelve months, with the number of treatment sessions varying from a minimum of eight sessions to being a part of an ongoing programme. Although not all participants showed a decrease in behaviours, all studies reported some measurable improvements for the majority of the participants.

In the general population there is a plethora of self-help materials available. These offer advice on how to recognise, cope with and combat a range of disorders including anxiety, binge eating and depression, but none have been developed for people with intellectual disability. In the general population, studies of GSH using CBT techniques have reported positive outcomes and have been endorsed by the Government as an effective means of combating depression (Department of Health, 2001a). The evidence base for GSH has been subject to a number of reviews. For the purposes of this thesis I have concentrated on reviews reporting RCTs that have focused on depression and anxiety. This includes the NICE guidelines' meta analysis of 18 RCTs in GSH (National Collaborating Centre for Mental Health, 2010), a meta analysis and meta regression of GSH Controlled trials (Gellatly, Bower, Hennessy*, et al*, 2007), a meta regression and meta synthesis of evidence

(Lovell, Bower, Richards*, et al*, 2008) and a comparison of GSH and face to face psychotherapies (Cuijpers, Donker, van Straten*, et al*, 2010; Kaehne & O'Connell, 2010) and a RCT of face to face GSH (Williams, Wilson, Morrison, *et al,* 2013). Although RCTs have reported a reduction in symptoms and remission rates in the general population (National Collaborating Centre for Mental Health, 2004), there is no current consensus as to what is the most effective, design, content and way to engage or deliver GSH to bring about best outcomes.

The NICE guidelines (National Collaborating Centre for Mental Health, 2010, pp. 184-187) reviewed 18 book based GSH using RCT methodology. Two of the studies reported a beneficial effect for those with mild depression and sub threshold depression, trending towards statistical significance. The five studies characterised by frequent support with minimum duration reported a large effect when reporting reduction of depressive symptoms with waiting list controls. The other studies considered had insufficient data and wide confidence intervals (CI), to be able to reach any meaningful conclusions. The meta-analysis within the NICE guidance has been reproduced in Table 1-5 below; reporting inconsistencies reflect gaps in how the data is presented within the original report. Of the eighteen RCTs that met inclusion criteria, two examined individual GSH with guided support, ten individual with minimal support, three groups GSH (psycho education) and three GSH by mail.

Table 1 Individual GSH with support - 89 participants 2 studies

		N/% Fem./Mean Age	Inclusion	Intervention	Control	Length of treatment	Follow up	Results
1	Brown 1984	30/55/37	Major depressive disorder (MDD)	Coping with Depression (CWD) individual support	Waiting List	8 weeks	1 and 6 months	SMD -0.28; 95%, CI --0.88, -0.34 (BDI)
2	Lovell 2008	59/73/38	GP diagnosis + BDI >14	Individual GSH	Treatment as usual (TAU)	12 weeks mean	Not reported	SMD -0.98; 95% CI -1.50, -0.47

In the tables relating to GSH with minimal support, results for individual studies have not been included, this is because data had been grouped. In terms of comparison; GSH v waiting list K = 6, n =227, RR 1.71 (0.62 to 4.49), SMD-0.98, (-1.50 to -0.47), whereas GSH v TAU K =2, n-497; SMD -0.49 (-0.77 to -0.21) at 12 months SMD -0.42 (-0.70 to -0.14). Only the study by Williams is reported separately SMD -0.49; 95% CI - -0.77, --0.21 and SMD -0428; 95% CI - 0.70, -0.14 at follow up. There was insufficient evidence to reach conclusions from the group psychoeducation GSH studies. For self help with support, results were grouped K=3, n =368, RR 1.75 (0.67 to 4.56), with SMD -0.57 (-1.02 to -.012), at one month SMD -0.08 (-0.30 to 0.13) at three months SMD 0.02 (-0.38 to 0.42) and at six months SMD n-0.32 (-0.62 to -0.02). Overall the reported evidence across all studies in general was thought to have a beneficial effect in adults with mild and sub threshold depression.

Table 2 Individual GSH with minimal support-904 participants 10 studies

		N/ % Female /Mean Age	Inclusion	Intervention	Control	Length of treatment	Follow up
1	Beutler 1991	63/70/47	MDD	Self directed therapy	Group CBT focussed expressive psychotherapy	20 weeks	3 months
2	Brown 1984	30/55/37	MDD = Sub threshold	CWD	Waiting List	8 weeks	1-6 months
3	Floyd 2004	46/76/68	MDD	Bibliotherapy Feeling good	Waiting List	4-12 weeks	3 months
4	Jamison 1995	80/84/40	MDD	Bibliotherapy Feeling good	Waiting List	4 weeks	3 months
5	Landreville 1997	23/87/40	74% MDD 26% Minor depressive disorder	Bibliotherapy Feeling good	Waiting List	4 weeks	6 months
6	Schmidt 1983	34/86/42	No formal diagnosis BDI>10	Bibliotherapy Self help manual	Waiting List	8 weeks	10 week
7	Scogin 1987	29/79/0	No formal diagnosis HAMD >10	Bibliotherapy Feeling good	Waiting List	4 weeks	1 month
8	Scogin 1989	67/85/68	No formal diagnosis HAMD >10	Bibliotherapy Feeling good	Waiting List	1 month	6 months
9	Willemse 2004	216/66/42	Sub threshold depression	Minimum contact based on CWD course	TAU	60 days mean	12 months
10	Williams 2008	281/68/41	No formal diagnosis BDI >14	GSH	TAU	120 days mean	12 months

Table 3 Group guided self help (psycho education) 495 participants 3 studies

		N/ %Fem. /Mean Age	Inclusion	Intervention	Control	Length of treatment	Follow up
1	Brown 2004	120/93/ N/A	No formal diagnosis BDI>10 (70%)	Psycho education workshop	Waiting List	1 day mean	3 months
2	Hannson 2008	319/73/44	Depression	Psycho education contacts	TAU	6 weeks mean	Not reported
3	Schmidt 1983	32/86/42	BDI>10	Self Help Group (large)	Waiting List	8 weeks	10 weeks

Table 4 Self help with support by mail, 368 participants, 3 studies

		No/%Fem./ Mean Age	Inclusion	Intervention	Control	Length of treatment	Follow up
1	Geisner 2006	177/70/19	No formal diagnosis BDI>14	Personalised feedback and brochure by mail	Waiting List	Not reported	4 weeks
2	Salkovskis 2006	96/80/40	No formal diagnosis BDI>10	Tailored workbook	Waiting List	Not reported	4 weeks, 12 weeks and 6 months
3	Stice 2007	95/70/18	No formal diagnosis	Bibliotherapy Feeling good	Waiting List	30 days mean	6 months

Gellatly, Bower, Hennessy, *et al* (2007), examined the role of moderators on effectiveness of GSH e.g., patient populations, study design, intervention content and compared RCTs versus controls in the treatment of depressive symptoms. In all 34 studies were identified which included 39 comparisons. Greater effectiveness was associated with a number of factors including: recruitment outside of clinical settings, those with a diagnosis of depression rather than people at risk of depression and use of CBT techniques. Cuijpers, Donker, van Straten, *et al* (2010) meta-analysis of RCTs compared GSH with face-to-face psychotherapies for depression and anxiety disorders, consisted of 21 studies, with 810 participants, and reported the

mean effect size in favour of GSH *d=-0.02* (95% CI: -0.20~0.15, *n.s*). In terms of delivery, Lovell, Bower, Richards*, et al* (2008a) found no evidence that the number of sessions or how GSH was delivered e.g., mail, computer face to face was related to outcomes. However outcomes improved when GSH was based on CBT and those with mild to moderate depression were found to do better than those with a more severe clinical presentation. The overall effect of GSH was reported as medium, with standardised mean difference -0.43, 95% CI -0.57 to -0.30.

Since the updated review of RCTs of GSH, published in the NICE guidelines for Depression of RCTs, there has been one significant addition to the evidence; an RCT by Williams, Wilson, Morrison*, et al* (2013). This study aimed 1] to examine the acceptability of the intervention to "staff and patients" 2] bring about a decrease in mood related symptoms (at four months) and 3] demonstrate an increase in participant knowledge of depression. Participants (*N*= 281) were recruited from a range of G.P surgeries in Glasgow, UK. A psychology graduate facilitated face-to-face the GSH intervention, which consisted of three sessions with a fourth session available if required. People with learning difficulties and reading problems were excluded from the study. Eligibility included a BDI score of ≥ 14. Those meeting inclusion criteria were randomised to either GSH-CBT (*n*=141) or TAU (*n*=140). The GSH-CBT group were significantly less likely to suffer a deterioration in mood compared to the TAU group and 42.6% (43/101) of the GSH-CBT group maintained a reduction in BDI scores at four months follow up (compared to (25/102) 24.5%, for the TAU group (odds ratio 2.28, 1.25 to 4.17, p = 0.008). The follow up rate of 72.2% at four months decreased to 41-6% by six months. Of the GSH-CBT group, the number of sessions attended was *M*=2, *SD* 1.2. Only seven participants (7%) required a fourth session, and less than half (45%, 64) of participants attended all

three sessions, with 17% (14) attending two, 10% (14) one and 22% (32) failed to attend a single session. The mean duration of sessions 1-3, ranged from 40.2-42.7 minutes. Although the study did not include people with intellectual disability it has attracted positive media attention promoting GSH as an effective treatment http://www.bbc.co.uk/news/health-21083458.

Since the NICE guidelines on depression were originally published both GSH and self-help have received greater recognition and acceptance as a legitimate treatment modality for depression. A number of resources are now available e.g., the Northumberland Tyne and Weir NHS Foundation Trust, which has produced 23 titles on self help with video and audio introduction aimed at different at specific diagnosis including anxiety and depression along with more defined needs such as anger and sleep. The guides are produced in a number of formats and some titles have been aimed at specific groups such as prisoners, however there is nothing available within these resources for people with intellectual disability. These resources come in a variety formats and have been made freely available to download at http://www.ntw.nhs.uk/pic/selfhelp. With a range of resources like this now available it is reasonable to assume that the public are becoming increasingly aware and that self-help is becoming accepted. However often these resources are often not used in a systematic and/or ordered framework and often get confused with the superior GSH approach using CBT techniques (Gellatly, Bower, Hennessy*, et al*, 2007).

1.9 Evidence of GSH in intellectual disability

A reliance on proxy based reporting for people with intellectual disability has meant that self report has traditionally been ignored (Fujiura, 2012). The question as to whether people with intellectual disability can participate in treatment using psychological approaches has been a matter of debate for over 40 years.

During this time there have been dozens of examples of the successful use of CBT in treating depression, anxiety, panic disorders and phobias in the general population (Kaehne & O'Connell, 2010). It is only just over a decade ago that we were reminded that a diagnosis of intellectual disability was a diagnosis of exclusion in studies evaluating psychological therapies (Hollins & Sinason, 2000). Psychological interventions appear to have developed in practice in line with an increased understanding of how mental health needs affect people with intellectual disability (Hatton, 2002). There are five factors that have been put forward that are believed to influence the outcome of psychological therapy for people with intellectual disability (Mason, 2007):

- The perceived effectiveness of clinicians on psychological therapy
- Individual clinician competence
- Service resources number of clinicians
- The level of the client's disability
- The diagnostic overshadowing bias

Psychological therapies over recent years have been applied in a variety of ways to a wide range of mental health problems and behaviours for people with intellectual disability e.g., psychoeducational groups for psychosis, (Crowley, Rose, Smith*, et al*, 2008; Kirkland, 2005), depression, (Lindsay, Howells & Pitcaihly, 1993), anxiety

and cognitive behavioural anger treatment (Taylor, Novaco, Gillmer*, et al*, 2002; Taylor, Novaco, Gillmer*, et al*, 2005) and CBT for Sex offenders (Sex Offender Treatment Services Collaborative – Intellectual Disabilities (SOTSEC-ID), 2010). It has been argued that adaptation is not always necessary for psychological therapies aimed at people with mild intellectual disability (Dagnan, Chadwick & Proudlove, 2000), although a simplification of how interventions are delivered maybe necessary (Hatton, 2002; Wilner, 2009). This process has been termed "developmental adaptation" and involves the modification of language, goals, strategies and tasks (Thompson Prout and Nowak-Drabik, 2003).

It is too early to assume the effectiveness of CBT or other psychological treatment prior to testing on random samples in controlled trials (Sturmey, 2004) and in the absence of manualised approaches (Hassiotis, Serfaty, Azam*, et al*, 2011). Despite the rise in psychological based studies for people with intellectual disability, the evidence of clinical effectiveness for psychological interventions is still limited (Bhaumik, Gangadharan, Hiremath*, et al*, 2011). Although there have been encouraging results in areas like CBT for anger treatment, early psychotherapy research in people with intellectual disability (which is often qualitative in nature) has often been inconclusive or trended towards a conclusion that it is not effective in this group. Thompson Prout and Nowak-Drabik (2003), review of studies of face to face techniques for people with intellectual disability, concluded that this treatment was moderately effective or beneficial in people, with intellectual disability. However in clinical practice there is still no consistent agreement as to the degree of involvement people should have in their treatment (Soffe, Read & Frude, 2004). Agreement of the suitability of psychological therapies for people with intellectual disability is made more difficult because of past or current failures, which may not

be the fault of the person, but is down to how the treatment is constructed and delivered. The failure to consider individual needs and preferences has called into question the conclusions of studies that have dismissed the use of psychological treatments for people with intellectual disability (Thompson Prout & Nowak-Drabik, 2003).

There is no evidence of GSH being used specifically for people with intellectual disability. What evidence there is relates to psychological interventions that use self help. This has been limited to case studies, case series and small groups. These generally have reported good outcomes using self report measures and self guided supported treatment outside of formal sessions. The published examples have included a controlled trial of individual cognitive behavioural treatment for a group of male sex offenders. supplemented with a key worker, who was assigned to support those undergoing treatment with homework tasks designed to reinforce the sessions and practice the techniques learned e.g., relaxation (Taylor, Novaco, Gilmer, *et al*, 2002). Another example is a case study which details a complex intervention for fire setting (Clare, Murphy, Cox*, et al*, 1992). The aim was to provide the person with a range of self help techniques that they could learn continue and continue to use independently upon discharge. The techniques used included breathing exercises, a tape recording and how to use a help line (Samaritans). At the 30 month follow up point there was no evidence of any hoax calls or fire setting.

To summarise to this point, it is clear that there is a considerable burden of mental health problems in the ID population. These conditions can be difficult to diagnose but there are now a large number and range of health status measures for people with intellectual disability, although the reliability and validity for many is unknown (Riemsma, Forbes, Glanville*, et al*, 2001). The current literature reports the

successful use of various self-monitoring and stress management techniques including symptom diaries and the use of strategies aimed at reducing distress associated with common mental disorder as part of wider programmes. However there is still uncertainly in the absence of published evidence or clinical reports as to whether this applies to GSH because of the increased expectations on the individual to essentially manage their treatment with brief input from a facilitator.

While there is no existing GSH approach on which to draw, the wider literature and knowledge of the special requirements of the ID population does provide a helpful starting point for developing the SAINT. These considerations include that the SAINT materials should be presented in an easy read format, designed to encourage people with an intellectual disability to recognise and identify their feelings, particularly those that may cause or lead to distress and impact on the person's daily lives and mental health. Once feelings have been identified the person can be asked to select an appropriate coping strategy or intervention from a checklist of suitable items and to make a record in a record in a diary. This can also be used to say about things they may have done well or enjoyed during the day. This provides an insight into a person's mental health over a specified time period, to assist families, carers and professionals to monitor threats to mental well being, as well as the effects of the coping strategies used. The whole process can be completed with or without support. Although little training in use should be required, it is important that a manual is developed and produced in an accessible format to reinforce the process. Telephone support should also be available to participants and those supporting them.

CHAPTER 2 GENERAL METHODS

2.1 Introduction

This chapter provides an overview of the general methodology to develop and evaluate the SAINT. The three linked studies employed separate methodologies. This chapter outlines methodology common to all three studies.

The development of the SAINT follows the principles of the Medical Research Council (MRC) frameworks and guidance (Medical Research Council, 2000, 2008). Currently the literature for GSH is heavily biased towards intervention rather the development of specific GSH programmes. There is little evidence found describing the development of GSH using the MRC frameworks with limited exceptions. These include a study by Lovell, Bower, Richards*, et al* (2008), who have described the development of a GSH intervention for anxiety and depression using the 2008 MRC guidance and a study of GSH for children, which explores the feasibility and acceptability using the 2000 MRC guidance (Kendall, 2009).

The Medical Research Council (2000) guidance for complex interventions is considered to be the gold standard in terms of a methodology pathway from theory to long-term implementation. The framework and phases covered in the current study can be seen in Figure 4. This thesis addresses the first two phases of the framework Providing the results of the present thesis are encouraging the next stage would be to conduct an RCT to establish benefit compared to an alternative approach. The MRC guidance was revised in 2008 to emphasise the non-linear nature of research, as a four stage cyclic

model with a greater emphasis on reporting at each stage, (Medical Research Council, 2008), see Figure 5.

Phase number	Continuum of increasing evidence	Phase description	Phases completed during the current study
Phase I	Explore relevant theory to ensure best choice of intervention and hypothesis to predict major confounders and strategic design issues	Theory	• Literature review • Explore evidence of different GSH approaches • Consensus on contents of GSH contents by CE and SUE
Phase II	Identify the components of the intervention and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate and interact with each other	Modelling	• Tolerance and acceptability of the intervention • Fidelity - session attendance • Exploratory pilot using SCED to examine potential effectiveness
Phase III	Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention to an appropriate alternative	Exploratory Trial	
Phase IV	Compare a fully defined intervention to an alternative using a protocol that is theoretically defensible, reproducible and adequately controlled in a study with appropriate statistical power	Definitive RCT	
Phase V	Determine if others can reliability replicate your results in uncontrolled settings over the long term	Long term implementation	

Figure 4 MRC complex intervention guidance

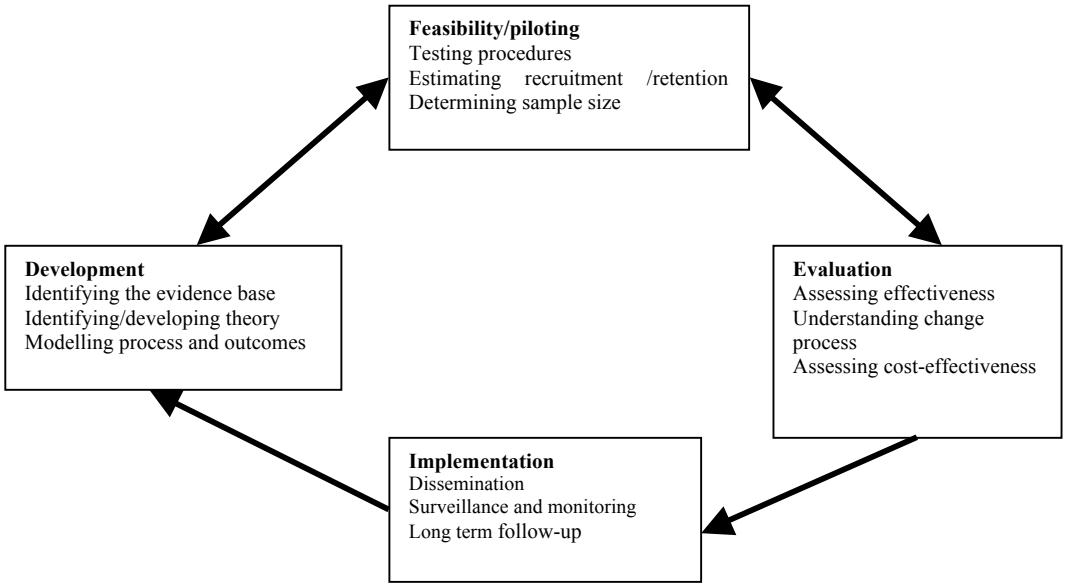

Figure 5 MRC updated guidance 2008

2.2 **Research design and methods**

Early intellectual disability research was largely ethnographic. Today these approaches are most common in studies to help understand and interpret the needs and behaviour of individuals who have profound communication difficulties and multiple handicaps. However there has been a shift in intellectual disability research from an activity where people are studied to one that has an increasing emphasis on participation. This mirrors the wider social context of inclusion for people with intellectual disability. Historically, exclusion was fuelled by the common belief that people with intellectual disability were unable to understand or contribute to research because of cognitive impairments.

The field of intellectual disability research is developing and there are currently a growing number of portfolio studies (studies funded by research bodies and charitable trusts) with a primary focus of intellectual disability and related conditions. However, there remains a limited evidence base derived from clinical trials and a need for more research. Adequate power to make an inference is difficult given that people with intellectual disability are a highly heterogeneous group who account for only 2% of the general population in England (Emerson and Hatton 2008). In spite of this people with intellectual disability have increased health needs and have a higher prevalence of mental health, physical health, genetic conditions and behavioural problems as well as increased rates of premature death. These issues constitute a unique challenge and demonstrate a need for a unified research strategy targeted at improving recruitment and development of multi centre RCTs. However there are still a number of issues that need to be addressed before this can become a reality. These include shortcomings in the organisation and scale of research, questions about the most appropriate method for collecting data and difficulties of adapting existing measures to the intellectual disability population. These are summarized below:

2.2.1 A lack of multi Centre studies and coordinated effort to set up multicentre clinical trials

Although there are a few examples of on-going multi centre studies into common genetic conditions associated with intellectual disability e .g., Fragile X syndrome, Down’s syndrome and other neurodevelopmental disorders such as Autism; a strategy to develop and organise clinical trial networks and speed translation of findings into clinical practice is not in place. Currently intellectual disability research is most

commonly built around partnerships between health care providers and universities. The lack of growth in multi centre studies, has contributed to a dearth of methodologically sound clinical trials that have often failed to have power to detect any clinical benefit. In terms of facilitating recruitment into quality clinical trials there needs to be an emphasis on education e.g. staff training on good clinical practice for drug and non-drug treatments. Competition for research funds has led to a tendency for institutions to work in isolation. The development of a national intellectual disability clinical trials network of partners from health, social care, medicine and third sector providers working in partnership with commercial and non commercial sponsors would encourage and develop expertise in clinical trials research with people with intellectual disability. Furthermore it would encourage the development of approaches to stratify this diverse population and thereby tailor clinical trials.

2.2.2 Lack of translation into clinical practice

A review of intellectual disability research in the UK over the last two decades has reported evidence of clear progress into research of mental health problems in intellectual disability although the translational impact of this research had not always been realised (Hemmings, Deb, Chaplin*, et al*, 2013). One example is the growing recognition that medication should not be prescribed as first-line treatment in people with intellectual disability who present with problem behaviours when there is no clear diagnosable mental illness (Tyrer, Oliver-Africano, Romeo*, et al*, 2009). Although these findings are widely accepted there is still an over relaince on the use of medication to treat CB.

2.2.3 Obstacles through misunderstandings of ethics committees and other bodies approving research

Research Ethics Committees may lack specific expertise in Clinical Studies Protocols relating to intellectual disability research. The potential of this vulnerable group to be exploited means that there is an increased need to ensure safeguards for participants within research protocols. However the need to protect should be proportionate, so it upholds the rights of the individual but at the same time does not make the process prohibitive (Nind 2008).

2.2.4 Targeting of specific groups

A clinical trials strategy and research pathway will allow understanding and to clearly define and focus on defined sub groups. Currently there are a number of multicentre research groups looking at specific groups such as offenders. However there is a lack of RCTs and studies with control groups being condicted. It may be one of the existing centres or a new collaboration may forward this agenda to improve the relationship between researchers across centres of clinical excellence exists.

2.2.5 Challenges of adapting research methods for people with intellectual disability such as interviews, questionnaires and focus groups

The increase in participatory research has meant that the application of qualitative methods is now a central consideration. Methods such as interviews and focus groups have previously come under scrutiny and it has been questioned whether they are reliable means of inquiry to seek the opinion of people with intellectual disability. However a review of approaches used in intellectual disability research that included interview, focus groups, questionnaire and survey, visual methods, life story/narrative

and ethnography/observation refuted this assumption (Nind 2008). The challenges of adapting these methods to enable the participation of people with intellectual disability are considered below.

2.2.5.1 Interviews

When developing interview schedules there is a need to ensure they are fit for purpose and consider the practicalities of administration. The aim of questioning is to ensure the person understands what is being asked and to obtain a response. When questioning people with intellectual disability there are a number of specific considerations e.g., is the question clear, is the language used accessible and when conducting the interview is the person given enough time to understand and respond. There is no consensus on the optimal style of questioning for people with intellectual disability and the level of functioning of the person often informs choice of style. In terms of approaches there are arguments against the use of open ended questions as they can make the person feel uncomfortable given the expectation of a fluent response. If a person is or feels unable to respond the use of direct questioning should be considered (Lewis 2002). Gudjonsson & Joyce, (2011) advocates the use of free narrative to allow the person to say what they need to and is the approach commonly adopted in semi structured interviews. The frailties of either approach can be mitigated to a certain extent by the skill of the interviewer in how they administer a questionnaire. For people with intellectual disability there is evidence of a number of aides to improve accessibility including pictures, symbols, cue cards and markers that divide the questionnaire. Ultimately the interview using whatever technique should be fit for purpose in that it attempts to get the necessary data to answer the research question.

2.2.5.2 Questionnaires

Questionnaires are supplied to participants to complete, and differ from interviews where an interviewee is responsible for putting forward the questions and recording responses. The use of questionnaires unmodified is not as common as interviews given the potential difficulties with the communication and understanding of participants (Nind 2008). To ensure validity of the questionnaire, a number of studies have used adapted methods to improve accuracy of responses. These include getting opinions by proxy i.e., from a representative of the person (McConkey & Mezza's 2001), the questionnaire is completed via face to face interview (Emerson, Malem, Davies & Spencer 2005, the use of visual cues such as photos or symbols. Adapting methods to suit the group being researched can increase authenticity and the validity and reliability of responses (Lewis 2002). The development of practical guidelines for Researchers when Interviewing People with an Intellectual Disability (D'Eath, 2005, American Association Intellectual and Developmental Disabilities 2009) http://www.fedvol.ie/_fileupload/File/Interviewing%20Guidelines(1).pdf 30.09.2013; have addressed a number of practical issues such as questioning style, to take into account the ability of the interviewee to generalise and articulate experiences, think in abstract terms and conceptual difficulty such as time. To ensure interview schedules are accessible and understood by intended participants, a number of basic principles need to be followed and includes:

- Keep the language clear and simple
- Try to keep to one idea per sentence
- Keep the sentences short
- Try to use the same word for the same thing
- Find out what the person's own words are for specific things
- Be supportive

(Gudjonsson & Joyce, 2011), p18

2.2.5.3 Focus Groups

Focus groups are an alternative method to interviews to gather information relating to people's experiences and opinions. They offer advantages such as peer support and are designed to generate discussion and are often thought of as less intimidating. In certain situations focus groups may be impractical, particularly if participants are widely spread geographically. For over a decade now there has been increasing evidence on the successful use of focus groups for people with intellectual disability (Barr McConkey & McConachie 2003). The success of focus groups can be compromised by a number of factors which include interdependence within the group, not addressing odd or challenging behaviours, failure to take into account the range of cognitive and social abilities and needs within the groups (Moonen, Kauppinen, Iyer*, et al*, PREPRINT) http://hada.ii.uam.es/umadr2010/drafts/2.-Rob-Moonen-Methods.pdf accessed October 2013. The recruitment and use of existing groups was decided upon as a way to address these potential issues. Fraser and Fraser (2001) recommended that for participants with communication difficulties smaller groups (6-10 participants) were indicated.

2.2.6 Challenges of lack of appropriate instruments/tools to measure psychopathology

In the last 30 years there has been a greater interest in the feelings of people with intellectual disability (Lindsay, Mitchie, Baty*, et al*, 1994). A greater awareness of mental illness in this group has coincided with the need for accurate measurement of psychopathology. It cannot be taken for granted that measures used in non-intellectual disability populations are valid and reliable for people with intellectual disability. There are a number of reasons for this, including the lack of normative data, a higher prevalence of mental health problems in intellectual disability population, atypical clinical presentation, levels of comprehension and the ability to understand what is asked of them (Cooper, Smiley, Morrison*, et al*, 2007; Cuthill, Espie & Cooper, 2003; Gitta & Goldberg, 1995; Stravrakaki & Mintsioulis, 1997; Sturmey, Reed & Corbett, 1991). Other confounders include the range of definitions of intellectual disability, differences in diagnostic criteria and the use of indicators that are less likely to be valid for people with intellectual disability such as employment, independent living and relationships. It is suggested that deficits in communication along with cognitive impairment may limit the self reporting of people with intellectual disability essential to the use of self rating anxiety and depression scales (Ramirez & Lukenbill, 2008). Currently there are a number of measures of psychopathology and behaviour in current use to assist diagnosis of people with intellectual disability. These can be divided into three groups:

1. Measures validated in the general population that are used unmodified for people with intellectual disability
2. Measures that have been tested in other populations but have been modified to attempt to make them accessible for people with intellectual disability
3. Measures that have been developed specifically for people with intellectual disability

Examples of measures validated in the general population that have been used in people with intellectual disability include the Beck Depression Inventory (BDI-II) and Beck Anxiety inventory (BAI), (Beck, Epstein, Brown*, et al*, 1988; Beck, Steer & Carbin, 1988), both of which have been reported to be acceptable for people with mild intellectual disability. Another approach has been to adapt existing measures e.g., the Hospital Anxiety and Depression Scale (HADS) (Dagnan, Jahoda, McDowell*, et al*, 2008). However it has become more common to develop measures specifically for people with intellectual disability such as the Psychiatric Assessments Schedules for Adults with Developmental Disabilities (PASS-ADD); (Moss, Prosser, Costello*, et al*, 1998).

In this current study five outcome measures were considered for use. These were the General Health Questionnaire (GHQ) (Goldberg, 1972), and four intellectual disability specific measures: the PASS-ADD, Camberwell Assessment of Need for Adults with Developmental and Intellectual Disabilities (CANDID) (Xenitidis, Thornicroft, Leese*, et al*, 2000), Glasgow Depression Scale for people with Learning Disabilities (GDS-LD) (Cuthill, Espie & Cooper, 2003) and Glasgow Anxiety Scale for people with Intellectual Disability (GAS-ID) (Mindham & Espie, 2003). The validity of the intellectual

disability specific measures considered is reported in appendix 1. Two of the measures considered were excluded early on in the process. These were the PASS-ADD, which is completed by an informant and therefore did not fit into the self report ethos of a GSH study; and the CAN-DID, which measures need and was excluded in favour of a more direct measure of symptoms. The three measures that were given further consideration were all self report based and are listed below.

2.2.6.1 Self Report Symptom Checklists

2.2.6.1.1 The GHQ

The GHQ has been translated and used across the world and in a number of different clinical areas, (Goldberg, Gater, Sartorius*, et al*, 1997; Pan & Goldberg, 1990). It is considered the gold standard in measuring psychological distress in the general population. However there are very few studies on the use of the GHQ in people with intellectual disability. Those studies there are have predominantly reported its use in people with borderline intellectual disability (Murphy, 2008), (Hatfield, Ryan, Pickering*, et al* (2004). A rare exception is a study by Lindsay, Mitchie, Baty*, et al* (1994), who reported on 67 people with moderate and mild intellectual disability, IQ level range (40-69) (*Mean age* 56.6 years), who were assessed using a number of measures. They reported the GHQ-28 to "relate consistently within its own factor system anxiety, depression and neuroticism", and also to other measures i.e., Zung Depression Inventory, Zung Self Rating Anxiety Scale and Eysenck-Withers Personality Test all of which "yielded scores to indicate presence of emotional problems, feelings and thoughts" This was a self report study with participants answering questions

independently, suggesting that self report by people with intellectual disability was extremely reliable and was at least on a par with the general population.

The lack of any evidence and information on the practical implementation of the GHQ in people with intellectual disability led to it being rejected in this study as an outcome measure.

2.2.6.1.2 The GSD-LD

The GDS-LD was developed specifically for use in an intellectual disability population. It is a 20-item questionnaire used to measure depressive symptoms in people with intellectual disability. Each question has a 3-point scale never/no, sometimes, always/a lot. Each of the 20 questions in the GDS-LD has four similar statements to provide examples in case of comprehension difficulties. The GSD-LD is reported to be able to differentiate well between depressive and non-depressed groups with and without intellectual disability and to correlate well with the Beck Depression Inventory (BDI) (Beck, Steer & Carbin, 1988). A systematic review by Hermans and Evenhuis (2010) found the GDS-LD appeared the most promising and reliable measure of depression for people with intellectual disability (internal consistency $a = 0.90$, test–retest reliability $r = 0.97$, sensitivity 96% and specificity 90%).

2.2.6.1.3 The GAS-ID

The GAS-ID (Mindham & Espie, 2003) is a 27-item questionnaire measuring three areas phobias, physiology and worries. In a systematic review or anxiety measures for people with intellectual disability to be the most promising, with good internal

consistency (*a*=0.96), high test–retest reliability (*r*=0.95), sensitivity (100%) and specificity (100%) (Hermans, van der Pas & Evenhuis, 2011).

The GAS-ID is similar to the GDS-LD in terms of implementation and both take between 5–15 minutes to administer, allowing participation and self report. The systematic reviews conducted by (Hermans & Evenhuis, 2010; Hermans, van der Pas & Evenhuis, 2011), each reported on the methodological quality and excellent reliability and validity of both of these measures. The ability to stand up to scrutiny against other measures was the reason that the GDS-LD and the GAS-ID were chosen as the outcome measures for this study. The worries sub scale was used as the outcome for anxiety, the sections relating to phobias and physiology were not used.

2.3 Inclusion/exclusion criteria for all studies

2.3.1 Inclusion criteria

- Aged over 18
- Intellectual disability defined as current user of intellectual disability services
- Clinical diagnosis of Mood (Affective) disorders F 30-39
- Symptoms of anxiety and/or depression as part of other ICD-10 F00–F99, mental and behavioural disorders, not listed in F 30-39
- Able to provide consent

2.3.2 Exclusion Criteria

- People suffering from head injury, post development
- People not known to intellectual disability services
- People who lack capacity[2]

2.4 Recruitment

The participants were recruited from specialist mental health in-patient, community mental health and residential services, for people with intellectual disability across the geographical areas covered by the South London and Maudsley NHS Foundation Trust, Hampshire Foundation Trust and Oxleas NHS Foundation Trust.

2.5 Ethical Approval

A favourable ethical opinion was received on the 23rd August 2008 (granted 20th August 2008) (08/H0809/43), from the Bexley and Greenwich Ethical Committee for all three parts of the project, see appendix 2. A substantial amendment to the study was submitted and approved by the South London REC office 5 on the 7th April 2011, see appendix 3. This was to [1] increase the number of participants recruited to the study to establish

[2] Although the central philosophy of the Mental Capacity Act (2007) is that everyone should be assumed to have capacity unless otherwise proved, where there is any genuine doubt a capacity assessment will be completed to determine participation. To address the issue of capacity the consent form used within the study has a capacity screen incorporated and is useful for those currently not using services and clinical judgment of the researcher. For those in hospital, a Psychiatrist will deal with issues of capacity.

reliability and validity and [2] to use a single case experimental design (SCED) during the pilot stage. The consent forms and information sheet can be seen in Appendix 4.

2.6 **Management of data and storage**

All data was stored on the King's College, University of London secure Drive and managed by the Principal Investigator (PI).

CHAPTER 3 STUDY 1 DEVELOPING THE SAINT

3.1 Introduction and aims

This chapter describes the development of the SAINT booklet and its contents following a consensus between two expert groups. Prior to the process for developing a consensus, key points for developing guided self-help were examined with a view to provide an overall context for the materials and intervention to be developed. These initial concepts of what the SAINT would look like in practice were shared with the two groups tasked with reaching consensus and incorporated within the methodology. There were four areas considered:

1. To engage the person in GSH materials
    a. This was addressed by involving people with intellectual disability to develop the materials. In particular to identify the issues that caused them distress, along with effective and realistic coping strategies they had used or heard about. The final sought a consensus from the two groups to agree and endorse a prototype of the SAINT
2. To identify the key problems and goals to work on
    a. The identification of key problems experienced by the person starts is prompted by a set list of feelings and emotions. The list is also designed to assist discussion at weekly sessions and to act as a prompt. The problems and coping strategies that were identified by the person were

to be incorporated into a diary section. The SAINT would not rely on standard templates but would be tailored to individuals. The rationale for this was to cut down the size of the manual so it was easier to understand and navigate and to get away from 'a one size fits all' approach.

3. To identify other appropriate self-help materials and mechanisms to aid review
    a. This meant additional materials such as information leaflets on common mental health problems and their management were to be available during sessions. Any additional exercises that were given as part of homework were to be recorded in the diary
4. To support the person
    a. Support would be available at weekly sessions, with additional support from carers and support workers between these times. A phone helpline would also be made available for those receiving the intervention and those supporting them; to answer any problems relating to either the manual or the process in general. Finally a training manual reference between sessions. The training manual was consciously made separate so not to clutter the SAINT manual.

There is currently no consensus or standards for GSH materials. However there are a number of GSH guides from the UK that together illustrate the structure and ingredients that need to be considered to develop an effective GSH package (Improving Access to Psychological Therapies, 2010; Lovell, 2000; Lovell & Richards, 2008; Bexley Care Trust, 2008). A lack of GSH materials for people with intellectual disability is in line with outdated ideas and perceptions often held about them. This lack of understanding

has hindered equity in accessing healthcare and the treatments received for people with intellectual disability. The belief that people with intellectual disability are unable to get benefit from psychological therapies has meant that they are excluded from treatment or that materials and processes have been presented without reasonable adjustments being considered. One example is the MIND Framework for Good Practice (Bexley Care Trust, 2008), *A step by step guide to delivering guided self help CBT*, where the referral criteria for GSH excludes people with low literacy levels. Rather than exclude the challenge is to involve people with intellectual disability by developing suitable GSH materials. Improving Access to Psychological Therapies, (2010) suggested guided self-help should involve:

- Engaging the person in guided self-help
- Identifying key problems and goals to work on
- Identifying appropriate self-help materials
- Supporting the person in their efforts to change
- Review progress and the need for further help
- Use of assessment and outcome measures to help assessment and review of progress

Self-help materials should be accessible, be understood, engage the reader, be factually accurate based on best practice and offer guidance (Improving Access to Psychological Therapies, 2010). This can be achieved in a number of ways such as breaking down materials into smaller steps, the use of symbols or pictures to assist understanding, being able to identify progress and being able to access other relevant information as required. The **s**elf-**h**elp manual for **a**nxiety and **de**pression (SHADE) (Lovell, 2000) is a good

example of a self help intervention in current use for people with mild to moderate depression and/or anxiety. It is designed to be used alone or with professional help and is a good example of a self help intervention incorporating cognitive behavioural techniques in general use. It is divided into four steps:

- Step 1 - recognise thoughts, physical symptoms and behaviours
- Step 2 - identify problems and goals
- Step 3 - select suitable intervention
- Step 4 - evaluate progress

The third step is broken down into a number of techniques designed to reduce negative thoughts and anxiety e.g., behavioural activation and relaxation. The manual also incorporates information on mental health, training and examples of how to use the manual.

3.2 **Methodology**

3.2.1 Sample

Two expert groups were recruited with the aim of informing the SAINTs contents. These were; [1] clinical experts (CE) in the mental health of people with intellectual disability and [2] service user experts (SUE), people with intellectual disability who have used mental health services.

3.2.2 Recruitment

The CE group was identified from two national intellectual disability networks, one of which specialised in mental health. The SUEs were recruited from two mental health support groups for people with intellectual disability, "The Tuesday Group" and the "Beat the Blues" group. Prior to recruitment the SUE groups, were visited to offer information about the study. Those who expressed an interest in joining the study were visited and given information on the aims of the study and the expectations of participants who agree take part. An independent person not involved in the research was used to explain the study to potential participants. Following this they were given a week to reflect on whether they wished to participate or needed ay further explanation or clarification about the research prior to being consented. Those who lacked capacity were excluded from the study.

The person used for the consent process assisted with data collection whilst the researcher facilitated the group. Although they were not directly involved in the research, Their function was to record answers during the session onto the flip charts and to tally participant votes on items to prevent researcher bias. No payment was made to participants however healthy food and snacks were provided for the sessions. Following the results both SUE groups were revisited and presented with the results.

The CEs were defined as those currently working with people with mental health problems with intellectual disability or those with extensive clinical/non clinical experience of the group.

Questionnaires and study information for the CEs were sent by email from an internet website www.surveymonkey.com, with evidence suggesting that web surveys significantly outperform email alone, (see Andrews, Nonnecke & Preece, 2003). The final questionnaire was developed from two prototype questionnaires that were piloted with three people (two senior Nurses and a research assistant all of who worked in specialist mental health services for people intellectual disability) to establish face validity. The first questionnaire used an 8-point scale. This was positively viewed in terms of completeness of information but was considered over inclusive and its categories were reported as difficult to distinguish. The second draft used a 5-point scale; "agree" to "disagree" was preferred. The middle rating, "don't know", was changed, following feedback to "neither agree" or "neither disagree", to imply neutrality of response. Questions that described events, circumstances, implied blame on others or were comments relating to the person's day were removed e.g., "It is an important day, I have an appointment', 'I have missed work', and 'if the others don't stop I will do something'. 'I have had no fits or seizures' were removed. The final questions were all phrased in the first person i.e., 'I feel' and reflected feelings that the individual may or may not be experiencing. The CE and SUEs group recruitment is illustrated in Figure 6.

Figure 6 CE group recruitment

In both rounds 2 and 3, five emails were returned undelivered. The SUE group contained nine people, seven, (77.8%) *males* and two, (22.2%), *females* all of who participated across the three rounds.

3.3 Procedure

The methodology used to reach a consensus on the SAINT, differed between the two groups. The CEs were canvassed using a traditional Delphi approach, whilst the SUEs participated through focus groups, which were adapted to incorporate Delphi principles, i.e., being able to consider and develop opinion following new information from other participants. The geographical distances between the CE participants meant that they were engaged via email and the Internet. This was not possible for the SUEs, the majority of who had no access to computers and those that did may have had difficulty with the process.

The Delphi consisted of three rounds of questioning, and was completed over a seven month period. The focus groups were also over three rounds and mirrored the Delphi in both the approach and timeframe. This was necessary so both groups could share and benefit from each other's responses. Consensus across both groups was reached over two rounds for the main contents of the SAINT. The third round was used to make final amendments and to reach agreement on the finer detail.

3.3.1 Delphi and Focus Groups

3.3.2 Focus groups protocol

As mentioned earlier the focus groups were organised using a facilitator and an assistant to record information. The groups followed the following protocol:

- Introductions and welcome
- Agree the ground rules (first meeting) e.g., confidentiality, one person speaking at a time, if you don't agree with others, you should let them put their point across and share their views. A recap of the ground rules occurred in subsequent meetings.
- An overview of topic and reemphasis of the purpose of the research
- Introduce the questions to the group and put participants at ease e.g., no right or wrong answers, only differing points of view. Encourage discussion.
- Draw the session to a close and seek final agreement with participants on the generated responses
- Give time of and outline the purpose of the next session

The Delphi and Focus groups were designed to reach agreement on the following two questions to inform the contents of the SAINT:

1. What are the ten signs and/or symptoms that are most likely to signal that the individuals' were experiencing mental distress
2. What are the ten coping strategies that have a positive effect on mental wellbeing

The CE group questionnaire comprised of statements relating to poor mental health and the use of effective coping strategies, which were rated in order of importance. The contents of the mental health questionnaires were informed by current rating scales, e.g., Beck Depression Inventory (BDI) (Beck, Steer & Carbin, 1988), Brief Psychiatric Rating Scale (BPRS), (Overall & Gorham, 1962), GDS-LD (Cuthill, Espie & Cooper,

2003). The coping strategies were informed from cognitive behaviourally based research (Haddock, Lobban, Hatton*, et al*, 2004; Lindsay & Lees, 2003; Sturmey, 2004; Taylor, Novaco, Guinan*, et al*, 2004) and everyday clinical practice for the CE group. In the SUE group a list of statements characterising poor mental health and effective coping strategies was generated from the group discussion. These responses were made up from the participant's own experiences and knowledge, rather than from symptom and intervention lists.

3.3.3 Analysis

For the CE group a ranking average of scores from a five point Likert scale was used, whereas the SUE's used a voting system to determine the most popular answers in order of perceived importance.

3.4 Results Study I

3.4.1 Delphi and focus group questions round 1

The CE and SUE groups focussed on two questions that related to mental health, with examples given to assist understanding:

1. How do people feel when they are becoming unwell? When do we know when we are at risk from becoming unwell? (Hereafter referred to as indicators)
2. What activities, coping strategies can help us to feel better about ourselves or help when we are feeling miserable or distressed?

3.4.2 SUE group 1 Greenwich 'Beat the Blues' round 1

This group was made up of people receiving mental health services within the local Community Learning Disabilities Team. Ten people attended the group, with seven consenting to take part in the study. The remaining three wished to participate in the group but not have their comments used as part of the study. Of the study participants, two had a moderate learning disability and five a mild intellectual disability. In terms of mental health diagnosis all had affective disorders (ICD-10, F: 30-39) with one person having a comorbid emotionally unstable personality disorder.

The group generated a total of 20 responses for the indicators question. These were a mixture of feelings and emotions and often related to events that had been experienced such as nightmares, being teased and people not liking them. The group used everyday language to articulate their responses such as; "I feel a bit rough", "I feel hot and cold", "I feel stressed out", and "I feel mad". The coping strategies question generated a total of 43 responses. Some coping strategies scored lower than expected e.g., talking to someone, as a number of the group reported they had no one they could trust to talk to in confidence. See tables 5 and 6 for detailed responses and items chosen by both SUE and CE groups.

3.4.3 Service User Expert group 2 Lewisham "The Tuesday Group" round 1

The second SUE group were made up of two service users who attended the local Trust mental health promotion group, both were male, had mild intellectual disability and a history of depression and anxiety. Twenty responses were generated for the first question on indicators, whilst the second question on coping strategies generated a total of 15 responses including talk to key worker, talk to family and friends, counselling, use

a stress ball, breathing exercises, go out for a trip, and someone gives me time with them. All responses were voted on and kept for the second stage without amendment and the participants agreed that all of the responses were good coping strategies.

3.4.4 CE Round 1

In total 38 Delphi questionnaires were completed. Of the respondents 55.3% (21) were female, and 46.7% (17) were male. Nurses accounted for 53.1% (17) of respondents; psychiatrists 25% (8), with the remainder made up of psychologists, occupational therapists, behaviour support workers, nurses and clinical academics. A rating average was used to rank the answers in order of popularity and scores ranged from 2.76–4.26. Any additional comments that were received were made available to all participants in the 2nd round of the Delphi. The coping strategies were also ranked using a rating average, this ranged from 3.05-4.55. Once again comments were made available for round 2. All responses from the CE were presented to the SUE groups to inform the second round with similar items grouped together.

3.4.5 Delphi and focus groups round 2

3.4.6 SUE results round 2

The results and feedback of both groups from round 1 were considered. In all 40 self report responses and 58 coping strategies from round 1, were considered. The groups were asked to rate the indicators and coping strategies and choose the 10 most likely to indicate poor mental health and most effective coping strategies. Fifty-eight answers were received from the two SUE groups the coping strategies that rated highest were listed.

To assist consensus from the SUE groups in round 2, responses from both groups in round 1 were listed alongside each other and colour coded to assist comparison. Both SUE groups retained all the self report statements from round 1 and chose their most and least helpful statements; 'Losing appetite', 'feeling anxious', and 'problems sleeping' were thought to be the most helpful.

3.4.7 CE results round 2

In the second round nurses (9, 40.9%) and psychiatrists (8, 36.4%) again comprised the two largest occupational groups. The questionnaire was revised to include comments from the SUE round 1 with similar items grouped. The rating average for the indicators ranged from 4.05–4.64 and 4.0–4.55 for the coping strategies.

A breakdown of results from both the CE and SUE groups are given below in Table 5 and 7.

Table 5 SUE responses rounds 1 and 2

	Round 1	**Round 2**
SUE Coping strategies	The top responses Beat The Blues 1=I feel hot and cold, 6 (8.6%), I feel stressed out (stress), 6 (8.6%), I feel tired, 6 (8.6%), 4= I feel dizzy, 5 (7.1%), I am not sleeping, 4 (5.7%), I am in pain, 4 (5.7%), 7= I have nightmares, 4 (5.7%), I have a temper, 4 (5.7%), I feel strange, 4 (5.7%), I don't know who you are, 4 (5.7%). The top responses for the Tuesday Group, , 'I feel run down, 'I feel physically unwell', 'I feel heartbroken', 'I feel mood swings', 'I feel uptight, 'I feel tense', 'I react badly to situations', 'I feel emotional', 'I feel I want to stop going out', 'I stop activities', 'I feel I loose interest in day to day life', 'I stay in bed', 'I loose concentration'. 'I feel worried', 'I feel anxious', 'I feel I have the shakes', 'I feel my heart pounding, 'I lose my appetite, 'I feel tingly, "I feel upset". A number of responses reflected as can be seen reflect personal experiences	Merged responses form both SUE groups I feel run down includes physically unwell, dizzy, pain, I feel tense includes stressed out, stress, tense uptight I lose my appetite I feel anxious this includes feeling worried, I feel my heart pounding, I feel hot and cold, I feel tingly, I have the shakes I feel emotional includes upset, mood swings, I feel heartbroken I feel strange will include I don't know who you are I am having problems with sleep nightmares, waking up, getting out of bed, I am not sleeping, I feel tired I have a temper will include I react badly to situations I lose my concentration I find it difficult to do things merged from I have stopped activities, I am losing interest in day to day life, I have stopped going out
SUE coping strategy.	1=Have a check up, 7 (8.4%), Day trips, 7 (8.4%), 3=Socialising, 6 (7.2%), Take pills, 6 (7.2%), Watch a DVD/TV, 6 (7.2%), Puzzles, 6 (7.2%), Keep busy, 6 (7.2%), 8=Relax /rest, 5 (6%). Call for Bill or Helen (pseudonyms) (nurses), 5 (6%), Shopping, 5 (6%) Music, 5 (6%), Keep busy e.g., go to work, have a massage, go job hunting, go to classes, use the computer, do exercise, listen to soft music, have aromatherapy (scented candles), ring the Samaritans, go out to pubs, clubs and discos, socialise with people and go on holiday	Speak to someone in your team includes having a check up, take pills, talk to key worker, see a counsellor have a check up, call for Bill or Helen Speak to some one outside your team you trust. This includes the Samaritans, talk to family and friends, some one who can give you time Socialise includes day trips, pub, disco and clubs Watch TV or DVD Listen to music includes soft music Keep busy. This includes job hunting, go to classes, use the computer, go shopping Do exercises. This includes sports and activities such as walking Relax and rest. This includes using a stress ball, breathing exercises, aromatherapy or scented candles, get some fresh air Do hobbies. This includes stamp collecting, puzzles Other reading, comforter such as cuddle a teddy, play games

Table 6 CE Group responses rounds 1 and 2

	Round 1	**Round 2**
CE Coping strategies	1= I have thoughts that I would be better off dead or of hurting myself in some way, 4.26, I want to die, 4.26, 2, I don't want to be alive, 4.24, 3, I feel like cutting myself, 4.11, 4, I feel like hurting myself, 4.08, 5, I am hearing things that are not there, 4.05, 6, I feel I cant go on, 4.03, 7=, I am feeling sad., 3.97, I am feeling bad about myself, 3.97, 9, I am having problems with sleeping, 3.89, 10=, I have trouble with sleeping., 3.87, I think people know what I am thinking, 3.87, I believe people can play with my thoughts, 3.87,	1= I have thoughts that I would be better off dead includes I want to die I don't want to be alive, 4.64, I am hearing things that are not there, 4.64, 3, I feel like cutting myself Includes I feel like hurting myself hurting myself in some way, 4.50, 4, I think people know what I am thinking includes I believe people can play with my thoughts I feel people can control me, 4.45, 5, I feel I cant go on, 4.36, 6, I feel like I am in a panic includes I feel anxious I feel anxious this includes feeling worried, I feel my heart pounding, I feel hot and cold, I feel tingly, I have the shakes, 4.27, 6, I find it difficult to do things includes I have stopped activities, I am losing interest in day to day life, I have stopped going out, 4.27, 6, I have stopped bathing and changing my clothes., 4.27, 9, I am having problems with sleeping includes I have trouble with sleeping. I am having problems with sleep nightmares, waking up, getting out of bed, I am not sleeping, I feel tired, 4.23, 10, I have been drinking and/or taking drugs includes I am getting drunk more than usual I drink to cheer myself up, 4.18
CE coping strategies	1, Talk to someone close to me, 2, Tell and remind myself how well I coped before in similar situations, 4.45, 4.55, 3, Ring someone I know to, 4.42, 4= Doing exercise, 4.29, Do relaxation exercises, 4.29, 6, Take deep breathes, 4.24, 7= Go for a walk, 4.21, Talk, 8, Visit a friend or family, 4.16, 9=Listen to music, 4.13, Ring someone for help on a helpline e.g., Samaritans, 4.13	1, Talk to someone close to me includes ring someone I know to talk to, 4.55, 2, Tell and remind myself how well I coped before in similar situations, 4.41, 2, Use a support group Speak to some one outside your team you trust. This includes talk to family and friends, someone who can give you time Ring someone for help on a helpline e.g., Samaritans, 4.41, 3, Speak or get help from someone in your team includes having a check up, ask about medication, talk to key worker, see a counsellor have a check up, call for CPN, 4.41, 4, Do exercises. This includes sports and activities such as walking, 4.36, 5, Arranging to go out with a friend Socialise, includes day trips, pub, disco and clubs or inviting a friend for dinner, 4.27, 6, Do relaxation exercises includes take deep breaths Relax and rest use a stress ball, breathing exercises, aromatherapy or scented candles, get some fresh air, 4.14, 7, Listen to music, 4.09, 8, Do hobbies. This includes stamp collecting; puzzles play games use the computer, 4.05, 10, Keep busy. This includes job hunting, go to classes, go shopping tidy up, 4.00, 9, Visit a friend or family, 4.00.

3.4.8 Delphi and focus groups round 3

3.4.9 CE and SUE: Round 3

Both SUE focus groups were given a prototype version of the 'SAINT', which contained the final lists of agreed responses from both the Delphi and focus groups. The prototype included instructions on how the SAINT was intended to be used and consisted of ten self report statements and ten coping strategies. Each of the statements and strategies included a minimum of five examples of alternative wording on the same theme. An example from the self report statements is provided below:

1. 'I have trouble sleeping' or 'sleeping is causing me problems'
    a. I am having nightmares
    b. I keep waking in the night
    c. I wake up very early
    d. I find it difficult to get to sleep
    e. I keep falling asleep during the day

The final task for the CE group was to reduce the examples from the 10 agreed indicators and coping strategies to 4 items, see Table 7, which gives examples relating to anxiety, sleep and feeling down.

Table 7 Examples of self report selection

	Keep	Delete	Response Count
Anxiety - I feel in a panic			
I feel my heart pounding	100.0% (12)	0.0% (0)	12
I feel hot and cold	57.1% (8)	42.9% (6)	14
I feel tingly	46.2% (6)	53.8% (7)	13
I have the shakes	83.3% (10)	16.7% (2)	12
I am sweating	66.7% (8)	33.3% (4)	12
Sleep - I have problems sleeping			
I have trouble getting off to sleep	100.0% (12)	0.0% (0)	12
I have trouble waking up	75.0% (9)	25.0% (3)	12
I keep getting up during the night	76.9% (10)	23.1% (3)	13
I am having nightmares	50.0% (7)	50.0% (7)	14
I feel tired all the time	83.3% (10)	16.7% (2)	12
Feeling down - I feel down today			
I feel sad	100.0% (12)	0.0% (0)	12
I feel worried	100.0% (12)	0.0% (0)	12
I feel tense	61.5% (8)	38.5% (5)	13
I feel stressed	83.3% (10)	16.7% (2)	12
I feel uptight	46.2% (6)	53.8% (7)	13

The raw data for study 1 is available on the accompanying CD.

3.5 Discussion Study 1

This first study achieved its aim to develop the contents of the SAINT by achieving a consensus of opinions from the two expert groups using both Delphi and focus groups methodology. The Delphi is designed to gain a consensus of opinion(s) over a number of stages. It is an iterative process usually completed by questionnaire where the participants have the benefit of a round up of results of previous stages and may change original responses in view of the new answers. Its purpose is to generate an answer to a given question and therefore particularly useful in areas that do not lend themselves to traditional scientific approaches (Mullen, 2003), or where there is limited evidence (Campbell, Cantrill & Roberts, 2000; Hemmings, Underwood & Bouras, 2009; Linstone & Turoff, 2002; Mohan, Slade & Fahy, 2004). There is no standard Delphi procedure and as a result a Delphi can contain anything upwards of two rounds of consultation to establish a consensus. There are however three broad stages common to the Delphi (Linstone & Turoff, 2002):

1. Exploration of the subject under discussion
2. Reaching an understanding of how the group views the issue
3. To explore disagreement

There have been limited studies using Delphi techniques within intellectual disability research (Hemmings, Underwood & Bouras, 2009). In what is thought to be the first Delphi study to seek the opinions of people with intellectual disability, Bonell, Ali, Hall, *et al* (2011) found it to be a legitimate tool in gauging the opinions of the group. How far and to what degree this is generalisable to those with lower levels of functioning i.e., people outside the mild range of intellectual disability, is not known. Bonell and

colleagues Delphi consisted of two rounds of questioning and reported a 25% drop out rate by the second round, whereas this current study using focus groups was able to maintain 100% participation for the SUEs.

The development of self help materials and research requires a partnership from which both sides can learn (Lucock, M., Barber, R., Jones, A.*, et al,* 2007). Using a single methodological approach for both groups would have been the ideal but was not possible for a number of reasons e.g., for the CEs there was a wide geographical disparity in location, with a lack of a common timetable. For the SUE group, the use of Delphi questionnaires would have been problematic e.g., difficulty accessing support to use computers and to complete and understand questionnaires. A Delphi questionnaire for SUEs in this current study would have been inappropriate, as it would needed to have assumed participants had a knowledge of a number of complex issues relating of mental health e.g., what is mental health and the recognition of factors that influence mental wellbeing. To address this and make the process accessible, Delphi principles were imbedded within a series of focus groups, to assist the consultation process and to address possible coverage bias and ensuring representativeness of the sample (Vicente & Reis, 2010). Focus groups are well recognised as a legitimate methodology for people with intellectual disability (Gates & Waight, 2007; Gates, 2011) and assuming the needs of the group and the methods used are carefully considered it is possible to gather reliable data on a number of issues. Focus groups for people with intellectual disability can be useful in capturing the participant's perspective of reality based on, their personal opinions, views and experiences (Kaehne & O'Connell, 2010) they are also considered effective in reaching a consensus of perspectives (McCallion & McCarron, 2004). The

user groups were able to benefit by reflecting on the answers and opinions of each other. Using a dual methodological approach helped to highlight differences in the thinking of the two groups e.g., those statements rated highest by the CE group reflected more severe symptoms e.g., someone wanting to hurt them self or wanting to die or experiencing psychotic symptoms. This may suggest that the CE were more likely to consider the question from a nomothetic rather than an idiographic perspective and made decisions based on the perceived probability of the potential adverse impact of each statement considered. The SUE group answers appeared to reflect their personal experiences, with a number of responses in the form of metaphors e.g., "I have the shakes", this is common when describing symptoms, (see Kadam, Croft, McLeod*, et al*, 2001). A number of the group had difficulty understanding certain symptoms, such as hearing voices. The difficulty in conceptualising symptoms is not unique to people with intellectual disability, e.g., other studies have made this point relating to self-esteem and motivation (Glasman, Finlay & Brock, 2004). The opportunity to listen to the experiences and opinions of others in the group appeared to help participants gain an understanding of a range of symptoms and/or coping strategies they had previously not understood or heard of. The discussion allowed acknowledgment as to how coping strategies could be helpful for some but might be ineffective or could even make others feel worse e.g., gardening. This discussion was helpful for the group to make informed choices as to what include and reduce the likelihood of suggestibility.

The SUEs' responses were more likely to be in everyday language and drawn from personal feelings and experiences, reflecting how they might respond in any given

situation. The clinical groups were more likely to use terms that were consistent with their professional training and socialisation (Wolfsfeld & Haj-Yahia, 2010).

The retention rate for the CEs who started the Delphi was, 39.5%, this compares to 100% for SUEs. Of the 79 intended CE recipients, 38 (45.5%), participated in round 1, with 15 (19%) left, by round 3. A number of those identified to be invited to participate were unable to be contacted using the email addresses provided. Although this is a weakness of the approach, email is a legitimate method for conducting research but like traditional mail services it can offer significant challenges to recruitment and often has lower response rates that traditional postal surveys (Couper, Traugott & Lamias, 2001), with rates of 20% not uncommon with higher rates of retention associated with organisational studies (Andrews, Nonnecke & Preece, 2003). Email is often used where postal addresses are not known or for convenience and to reduce costs. There is no general agreement as to how many experts are needed to complete a Delphi consultation and it can be assumed that those who accepted the invitation to take part were both interested and experts in the area, this, prevents findings becoming skewed by the recruitment of participants not representing the intended body of opinion (Streiner & Norman, 2008).

In terms of reflecting on what services users want and expect from self help, a number of key themes emerged from the focus groups. These included promoting good mental wellbeing, being in control, having access to support, taking advice and following treatment, having meaningful day activities, such as a job or college and to be independent. These themes are mostly consistent with previous service user research into self help and priorities for living, which has included; role and value of

relationships with other people, engaging with others support, medication, relationships with professionals, complementary therapies, religious and spiritual beliefs, access to self-help strategies, sport and physical exercise (Lucock, M., Barber, R., Jones, A.*, et al,* 2007).

CHAPTER 4 STUDY 2: ESTABLISHING RELIABILITY AND VALIDITY

4.1 Introduction and aims

This chapter reports on the second study to test the reliability and validity of the newly developed SAINT comparing it against the GDS-LD and GAS-ID (worries sub scale), widely regarded as the gold standards for self report depression and anxiety measurement in people with intellectual disability (Hermans & Evenhuis, 2010; Hermans, van der Pas & Evenhuis, 2011). The GAS-ID sub scales physiological reactions and phobias were omitted as being too specific and the worries sub scale was used to measure generalised anxiety.

The SAINT booklet contains 40 pages (Excluding cover). It is divided into four sections, which are published in A5 format. There are also A4 and coloured versions produced for people with visual impairments or those who prefer an alternative format, which were available on request. The four sections of the SAINT contain:

1 Personal details the purpose of the SAINT and the instructions for its use

2 Ten self report statements (indicators) made up of a list of behaviours, feelings and emotions. Each of the 10 items has 3-4 examples to aid explanation

3 Ten coping strategies which participants are encouraged to use if they have identified any of the indicators from the self report section

4 A diary to record any identified feelings from the self report section and the coping strategies used. The diary also promotes the recording of positive experiences e.g., achievements, things that went well or just the absence of any negative feelings or experiences

4.2 Methodology

4.2.1 Recruitment

The following methods were used to recruit to this stage of the study:

1. Letters to residential service providers for people with intellectual disability (*n*=36), followed up by phone calls
2. Approaches to the clinical leads of local specialist mental health services for people with intellectual disabilities
3. Approaches and presentation to outside agencies (regional Mencap, local authority, independent sector providers)

Sixty-eight participants were recruited from local services to form a purposive sample based on the study eligibility criteria. Of these, seven participants dropped out pre study, five lacked capacity, one person declined to participate and one

person became unwell, leaving a total sample of 59 participants, see Figure 7. Local providers of independent and supported accommodation were approached by mail to gain permission to approach potential participants to participate in the study. However no participants were recruited in this way. Despite follow up phone calls to residential settings access to potential participants was denied. The most common reasons given were the person lacked capacity or that they would not be interested in participating.

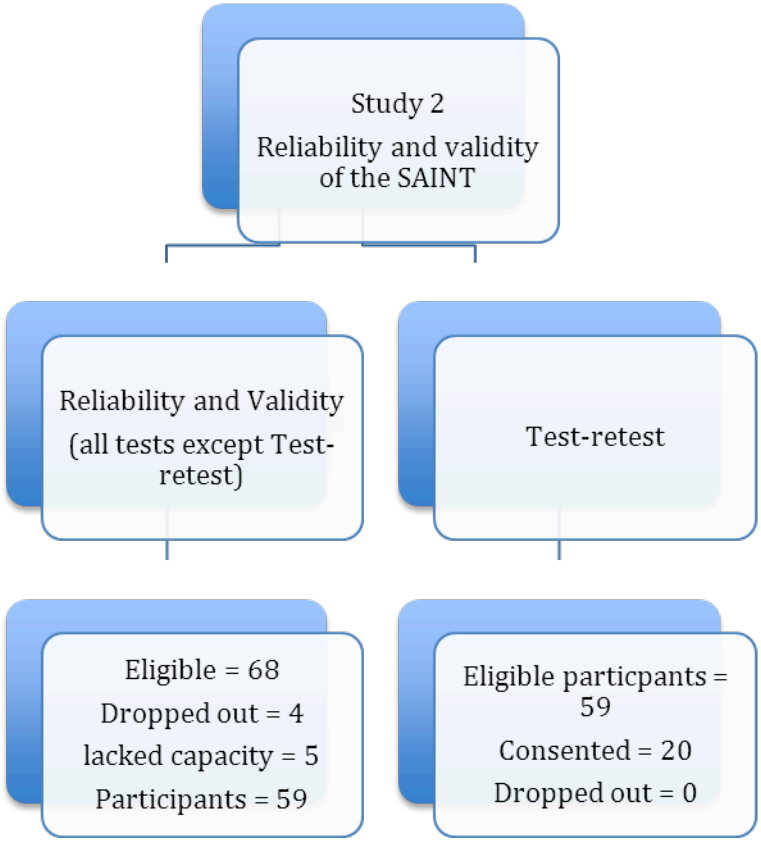

Figure 7 Reliability and validity recruitment

4.2.2 Procedure

The GDS-LD (Cuthill, Espie & Cooper, 2003a) and GAS-ID (Mindham & Espie, 2003) and SAINT, were administered by the researcher to all 59 participants, face to face. The data were tested for normal distribution, before reliability (which

examines consistency of the measure) and validity (which examines to what degree the measure, measures what it is intended to do) testing. Of the 59 participants, 55 were recorded in case notes and personal files as having a mild intellectual disability, with the remaining four having moderate intellectual disability. Participants were aged between 18 and 77, (M= 38.7 years, SD = 13.845). Male participants (n=35, 59.3%) were aged 18 to 68 (M =37.63 years, SD = 12.818). Female participants (n=24, 40.7%) were aged 18 to 77 (M= 40.42, SD = 14.815). The reliability and validity relating to this study is explained below and summarised in Table 10prior to the discussion.

4.2.3 Reliability and validity

To examine construct validity, i.e., how the SAINT measures feelings, and provides evidence for the construct, (in this case depression and anxiety), the SAINT was compared against the GDS-LD, and GAS-ID. These are both adjectival scales that measure levels of distress and/or wellbeing relating to depression and anxiety. Convergent validity was also tested to determine the degree to which the SAINT correlates with the other measures of the construct i.e., GDS-LD and GAS-ID. Content validity was also examined to see if the measure is likely to measure the areas for which it is intended. The SAINT's content and consensual validity was tested within the SUE and CE consultation. The results from the consultation informed the SAINT prototype, which was reviewed by the local speech and language team to assess suitability and accessibility for people with intellectual disability. The criterion validity of the SAINT was tested against the GDS-LD and GAS-ID to establish its ability to correlate with valid measures of anxiety and depression, collected at the same time. This is to examine correlation and relationships to measure concurrent validity which is part of the criterion

validity process. Finally test-retest reliability was tested over the period of one week. A smaller sample was examined for comparison purposes over the period of a day to look at differences in scoring of test retest as reported previously using the GDS-LD (Cuthill, Espie & Cooper, 2003).

4.2.4 Analysis

Analysis was conducted using a variety of statistical tests to assess the following:

- Normality –to test if the data were normally distributed and to inform if the use of parametric or non parametric tests was appropriate
- Correlations - to test the strength of relationship between the SAINT and both the GDS-LD and GAS-ID (worries subsection)
- Test retest - to test the reliability, consistency and stability of the measure over the period of a week.
- Internal consistency - to measure if the SAINT items are related and examine whether they measure the same construct
- Split half reliability – to test consistency. For this test the SAINT items are split into two halves and the scores for each half with the scores compared with each other
- Factor analysis - to examine the factor structure of the SAINT and to support reliability analysis

4.2.5 Results 2: Reliability and validity Test for normality

The data for the SAINT, GDS-LD and GAS-ID was tested for normal distribution using the Kolmogorov-Smirnov Test, D (59) = .174, $p < .000$, as the test result is significant i.e., lower than or equal to 0.05, this indicates that the data is not

normally distributed. The boxplot, see Figure 8 gives a graphical representation of the distribution of the data from the SAINT and confirms the above test.

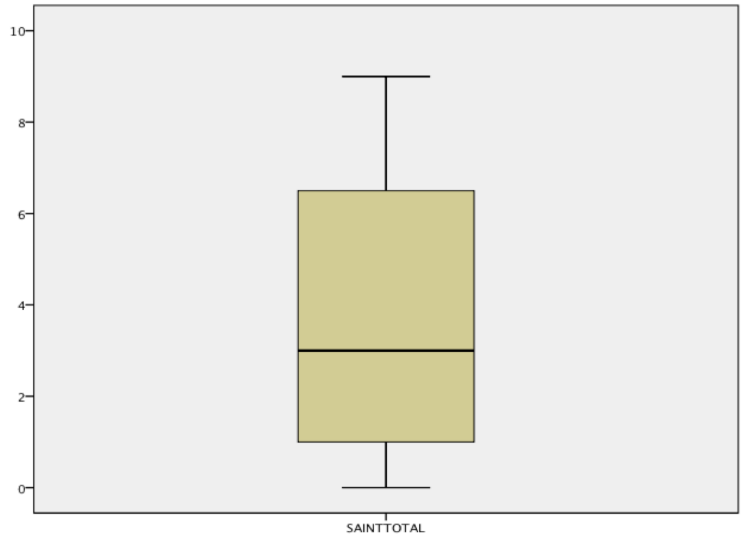

Figure 8 Boxplot SAINT

4.2.6 Correlation

The Spearmans' Rho was used to investigate the strength of the relationship between the SAINT total score; GDS-LD total score and GAS-ID for worries subcategory. The SAINT showed significant correlation at the levels, (2-tailed) with the GDS-LD (r = 0.619, p <0.001), GAS-ID (Worries) (r = 0.496, p <0.001). The correlation between GDS-LD and GAS-ID was also significant (r = 0.584, p <0.001). As well as showing a positive relationship it also shows direction of the scale i.e., it implies that the scores increase in line with total scores.

4.2.7 SAINT Test Retest

The Spearman's Correlation Coefficient was used to explore the strength of the relationship of the SAINT test-retest reliability on twenty participants. Test retest was conducted at one week. Data for the test were collected at weeks 2 and 3 of the baseline phase; unless significant events were reported e.g., police involvement,

bereavement and self-injury not normally part of the person's presentation. Where these events occurred test retest was completed in the subsequent two weeks. There was a significant correlation between SAINT test and SAINT retest correlation over a week period on a sample of *N*=20, 0.811 at the $p < 0.01$ level (2-tailed) see Figure 9.

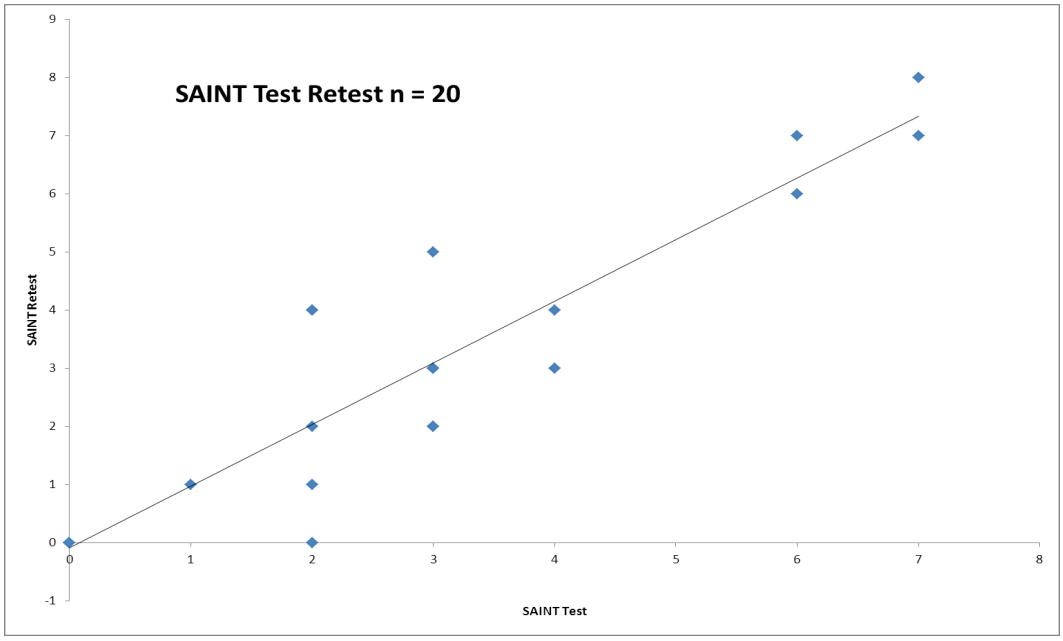

Figure 9 SAINT Test Retest Scatterplot

4.2.8 Internal Consistency

The reliability of the SAINT was investigated for internal consistency using Cronbach's alpha. The Cronbach's alpha score for the SAINT's 10 items was = 0.828 suggesting good internal consistency and reliability for the questionnaire. The reliability of the SAINT scale if any 1 item is deleted ranged from 0.798-0.830, which is within the optimal range for inter-item correlation (Briggs & Cheek, 1986). Mean scores for any item deleted ranges from 2.92–3.19. In comparison the Cronbach's alpha for the GDS-LD in this current study was 0.857, (0.839–0.860, for any item deleted) and for GAS-ID (worries subscale) was 0.844, (0.823–0.842, for any item deleted).

4.2.9 Split half reliability

Split half reliability was conducted using the Cronbach Alpha. Both sets of five items were consistent at .696 and .683 respectively.

4.3 Factor Analysis

Factor analysis can be seen to contribute to establishing construct validity. The matrix of intercorrelations that are inherent in factor analysis are used to examine how the construct can be divided into specific factors that can offer additional meaning by breaking down the construct (Cronbach and Meehl, 1955). There are a number of conditions that need to be met prior to conducting factor analysis. This is to improve accuracy and generalisability of the results and to lessen the chance of error. Factor analysis has traditionally been performed on large samples of 100 or more participants, MacCallum, Widaman, Zhang & Hong, (1999). For smaller samples there is the subject to variable ratio (STV). The ratio required is debated (see Garson 2008). Two common STVs is the 'rule of 10' 10:1 and the 'rule of 5' (5:1). This formula represents the number of cases per variable within the scale. An STV of 5 is considered the lower limit (Bryant and Yarnold, 1995), and this current study has an STV of 5.9:1. This satisfies the minimum data requirements for factor analysis providing a ratio of 5.9 cases per variable.

The Kaiser-Meyer-Olkin (KMO) and Bartlett's Test of Sphericity are measures of sampling adequacy that determine whether factor analysis is appropriate. The results from both tests supported factor analysis. The Bartlett's test of sphericity was significant (χ^2 197.56 df=59, $p < .01$, whilst the more discriminating index of

factor analysis, the KMO, was .761, above the recommended values, which range between 0.5 and 0.6),

The factorability of the 10 SAINT items was examined. Firstly, it was observed that 6 of the 10 items correlated at least .3 with at least one other item, suggesting reasonable factorability. The communalities were all above .45, with 7 items scoring above .6, see Table 8. This offers further confirmation that each item shared some common variance with other items. Given these overall indicators, factor analysis was deemed to be suitable for all 10 items.

Principal components analysis was used to identify and compute composite scores for the factors underlying SAINT. The first three factors with eigen values >1 explained 40.44%, 12.84%, and 10.15% of the variance respectively. Whereas the fourth, fifth and sixth factors, accounted for 5.5-8.9% of the variance. Solutions for three, four, five and six factors were each examined using varimax and oblimin rotations of the factor loading matrix. The three factor solution, which explained 63.4% of the variance, was preferred because of its previous theoretical support; the 'leveling off' of eigen values on the scree plot after three factors and the insufficient number of primary loadings and difficulty of interpreting the fourth factor and subsequent factors see Figure 10.

Table 8 Communalities

SAINT Items	Initial	Extraction
I am having bad thoughts	1.000	.734
I am not feeling myself	1.000	.488
I feel in a panic	1.000	.533
I find it difficult to do things	1.000	.647
I am having problems sleeping	1.000	.565
I feel down today	1.000	.642
I don't feel in control	1.000	.657
I feel bad about myself	1.000	.677
I feel emotional	1.000	.774
Looking after myself	1.000	.626

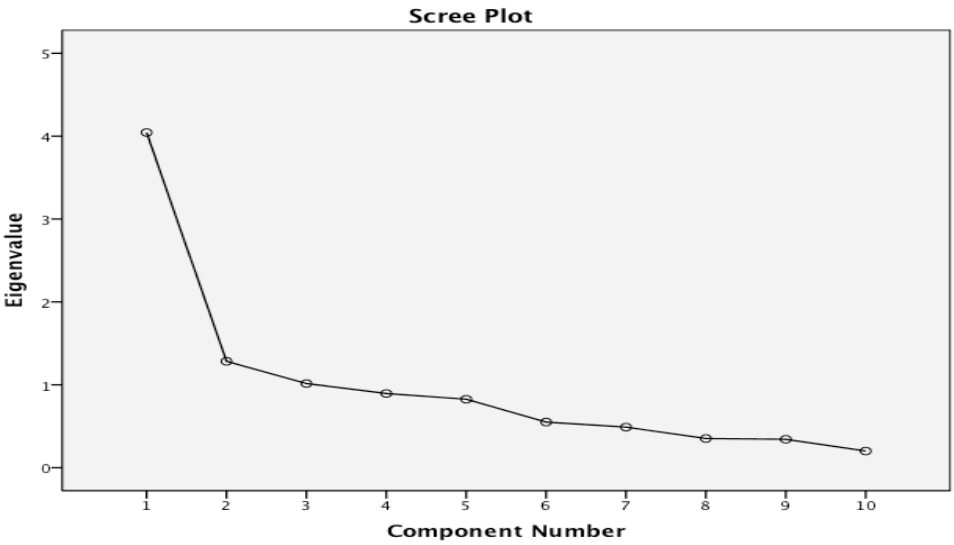

Figure 10 Scree plot

The rotated component matrix identified the following factors, which can be seen below see

Table 9. The factors have been labelled [1] negative ideation affecting activities of daily living, [2] feelings of losing control and [3] milder symptoms.

Table 9 Identified factors and rotated component matrix

1	Negative thoughts affecting activities of daily living	2	Feelings of losing control	3	Mild symptoms	
	S10-Looking after myself	.774	S7-I don't feel in control	.790	S6-I feel down today	.536
	S4-I find it difficult to do things	.765			S8-I feel bad about myself	.392
	S3- I feel in a panic	.660	S1- I am having bad thoughts	.779	S9-I feel emotional	.876
	S6-I feel down today	.559	S2-I am not feeling myself		S5-I am having problems sleeping	.702
	S1-I am having bad thoughts	.311		.683		
	S8-I feel bad about myself	.500	S8-I feel bad about myself	.524		

	Items overlapping	1	2	3
	SAINT10	.774		
	SAINT4	.765		
	SAINT3	.660		
	SAINT6	.559		.538
	SAINT7		.790	
	SAINT1	.311	.779	
	SAINT2		.683	
	SAINT8	.500	.524	.392
	SAINT9			.876
	SAINT5			.702

Table 10 Summary of reliability and validity

Type of reliability or validity	Rationale	Test(s)	Results *sample size n=59, unless otherwise stated*
Internal Reliability	How consistent the measure is with itself	Split half, internal consistency	Cronbach's alpha. Internal consistency for the SAINT's 10 items was = 0.828 Split half, both sets of five items were consistent at .696 and .683 respectively.
External Reliability	How a measure varies from one use to another	Test retest	Test retest two time periods Spearmans (n20) significant correlation over a week 0.811 at the $p < 0.01$ level (2-tailed)
Inter rater reliability	Measures reliability between raters	Five cases assessed by two expert raters	100% agreement. However this may reflect the dichotomous nature of the questioning
Face Validity	On the surface does it appear to measure what it is intended for.	Expert opinion	The materials were devised through the Delphi consultation. Prior to piloting the agreed contents were also examined by the speech and Language team
Criterion Validity –	assesses validity by comparing results against other measures e.g., GDS-LD, GAS-ID	Correlation	Spearman's (2-tailed) GDS-LD ($r = 0.619$, $p < 0.001$), GAS-ID (Worries) ($r = 0.496$, $p < 0.001$)

4.4 **Discussion Study II**

The aim of reliability testing is to examine how a measure performs consistently over time, whereas validity is tested to see if the measure does what it intends to do i.e., measure subjective distress. The SAINT showed good convergent validity with the GDS-LD and GAS-ID. This suggests that the SAINT is able to identify symptoms of depression and anxiety for people with mild intellectual disability.

Test-retest reliability is designed to estimate the error of measurement, or the range of fluctuation likely to occur in a single individual's score as a result of irrelevant, chance factors (Anastasi, 1988). The test generates a number between 0 and 1 where 1 is a perfect correlation. Acceptable scores will vary across settings from around 0.7 to 0.9. The SAINT showed a test retest correlation of 0.881 at the $p <$ 0.01 level (2-tailed). The time period between test retest has been debated in intellectual disability research. In the original reports of test-retest measures of the GDS-LD the retest was conducted after a short break on the same day (Cuthill, Espie & Cooper, 2003a). A short timescale for test retest opens itself for criticism as a high correlation may be due to memory recall, or practice effects (Bartels, Wegrzyn, Wiedl*, et al*, 2010). Although it could be argued that this may be compensated in some people with intellectual disability due to cognitive impairment relating to memory and recall.

In a scale where there it is expected that there will be little change over time (e.g., an IQ scale) a longer period between test and retest will be possible. However when measuring a variable such as mood, where change can take place over a short period of time, the challenge is to give sufficient time so that the retest result is not simply due to the participant recalling their answers from the earlier test, while

being sufficiently short to avoid any significant change in what is being assessed. There is no consensus on the optimum time for test retest and studies vary according to the constructs studied "most investigators have chosen an interval ranging from 2 days to 2 weeks (Marx, Menezes, Horovitz*, et al*, 2003). Another study that looked specifically at mood ratings studies reported timeframes of between 10 minutes to 24 hours between test and retest, with scores ranging from 0.32-0.89, with the shorter times between interviews performing better in terms of correlation. For people with intellectual disability cognitive impairments may also impact on the reliability of the assessment. With this in mind there have been examples within this group of very short periods between test and retest.

As part of development to support the reliability analysis, a factor analysis was considered to examine relationships between the variables of the SAINT. Factor analysis using Pearson product moment correlation with dichotomous data is a point of debate. In this study it was considered fit for purpose, as the purpose was not look to restructure or delete variables from the SAINT, as they had been constructed from SU and CE opinion. As this was a development study factor analysis was used to inform and support the reliability and validity analysis. This is a statistical method that produces factors from a set of observed variables. Exploratory factor analysis does not comment or provide a structure between observed variables and factors. Once identified those correlated items that comprise the factors need to be interpreted within the current evidence base.

Mental health assessment and treatment for people with intellectual disability is often more complex than in the general population for a number of reasons including atypical presentation, symptom heterogeneity and diagnostic overshadowing. This can be further complicated by difficulty in comprehension,

language, expression and conceptualisation (Lunsky & Palucka, 2004). This means symptoms such as guilt, low self-esteem, low self worth or negative ruminations are less likely to be reported if the person is less able to express themselves or unaware of the significance of these symptoms. In the assessment of mental disorder in people with intellectual disability there is extra reliance placed on a number of areas e.g., reports from others, physiological markers (sleep, diet etc.), as people with intellectual disability may be poor reporters or personal historians. CB may also be part of an atypical presentation of mental disorder. Symptoms may manifest atypically in the form of 'behavioural equivalents'[3], or occur secondary to the psychiatric disorder (Emerson, Moss & Kiernan, 1999). The concept of behavioural equivalents examines whether behaviours such as aggression, irritability and other CB, offer evidence of mental illness (Hemmings, Gravestock, Pickard*, et al*, 2006; Smiley & Cooper, 2003). Do such atypical behaviours in a mental health context point towards a diagnosis or are they in fact a natural reaction by the individual to their circumstances? The dilemma is whether these behaviours, should be incorporated within diagnostic schedules.

There is often overlap between symptoms of depression and anxiety and differentiating between symptoms of depression and anxiety can be problematic. To address this we have seen the development of tools that measure general psychological distress and mental well being as beneficial (Marshall and Willoughby-Booth, 2007). The SAINT comes into this category and was validated against specific scales of depression and anxiety.

[3] This is where a person's behaviour offers an indication or offers an association that symptoms are present (see, Sturmey, Laud, Cooper, *et al,* 2010).

CHAPTER 5 STUDY 3: SAINT PILOT STUDY

5.1 Introduction and aims

The third study tested the SAINT in practice and aimed to:

1. Establish proof of concept i.e., can people with intellectual disability use the approach?
2. See if using the SAINT reduced self reporting of depression and anxiety symptoms measured by the GDS-LD, GAS-ID and SAINT
3. Critically evaluate the SAINT in practice from the feedback of users and those supporting them using qualitative methodology. (This is covered in the next chapter)

5.2 Hypothesis

5.2.1 Primary hypothesis

The pilot study tested three hypotheses:

H1: The SAINT can be feasibly implemented in routine clinical services by recruitment across different care structures for people with intellectual disability and not fewer than 70% of those approached will accept offers of treatment.

H2: The SAINT is acceptable to participants as demonstrated by < 20% discontinuation from treatment and reported satisfaction with the process at the end of treatment

H3: The SAINT intervention is effective in terms of reductions in mean scores on measures of depression and anxiety (using the GDS-LD (Cuthill, Espie & Cooper, 2003), GAS-ID) (Mindham & Espie, 2003)) and the SAINT; and that a reduction in mean scores can be replicated in 1-3 participants who have previously received the intervention.

5.3 Methodology study III

5.3.1 An introduction to Single Case Experimental Design (SCED)

This study used SCED methodology, more specifically the A-B-A-B or reversal design. The four phases of the A-B-A-B design are outlined below:

- A-The condition (i.e., symptoms of depression and anxiety) are measured over a given period to establish a baseline. This measurement is also repeated in phases BAB.
- B-The intervention is introduced
- A-The intervention is discontinued
- B-The intervention is reintroduced

SCED has a history of use in intellectual disability research to evaluate behavioural interventions (Kellett, Beail, Bush*, et al*, 2009). The design is ideal for use in clinical practice as participants also act as their own controls. The aim of SCED is to

establish the effectiveness of an intervention on an individual over a period of time by examining their functioning during baseline and following an intervention (Borckardt & Nash, 2002). The ABAB aims to demonstrate the effect (A-B) and its replication (A-B), if the predicted patterns are confirmed and not through chance then a strong inference can be made that improvement is caused by the treatment (Borckardt & Nash, 2002). This design is preferable to other single case designs in that it demonstrates more than a before and during (A-B design) and is able to replicate its findings unlike the A-B-A design. SCED methodology assumes that the results from treatment will be reversed. The A-B-A-B or reversal design, used in this study examines the impact of reintroduction of the intervention and aims to establish evidence of positive effect evidenced by either visual or statistical analysis and its replication. One of the limitations of ABAB designs is possible carry over effects e.g., the feel good factor produced by the intervention may last well into the next phase when the intervention is withdrawn; it may also be the case if the intervention stage is not long enough then there is little time to demonstrate any improvement from the intervention. However with interventions such as coping strategies e.g., relaxation that works on the day this type of issue is less likely to occur. The use of SCED in GSH research is unusual and possibly unique to this study. Best evidence for GSH so far as come from RCTs. Other study methods used include comparison of GSH against controls, (Komatsu, Hayashi, Suzuki*, et al*, 2012), descriptive studies (Pritchard, Bergin & Wade, 2004) and materials published where there is little or no evidence of effectiveness (Anderson, Lewis & Araya, 2005; Whitfield, 2006).

Horner et al. (2005), describes SCED as "…experimental rather than correlational or descriptive and its purpose is to document causal, or functional, relationships between independent and dependent variables". SCED should not be confused with case studies and/or case series, which retrospectively report the results of a specific treatment episode in practice and lacks a scientific approach. SCED can address a broad array of questions such as feasibility, proof of concept, hypothesis testing and building. The approach looks at the effect of an independent variable on the dependent variable. Unlike a RCT, SCED lends itself to modification by adjusting and changing of the independent variable to understand the intervention profile. With no set standards, SCED designs vary in complexity from basic comparison to complex crossover designs. The SCED can act as a viable alternative to RCTs. It is quicker to implement, less expensive and it can provide information for any future RCT by building evidence through replication. To reduce heterogeneity and define samples, SCEDs are built up upon and based on key features of the person(s) studied and control for threats of internal and external validity through systematic replication. Internal validity in SCED relates to the study design, its definitions, and implementation, it provides confidence that the results from the study can be attributed to the independent rather than extraneous variables.

Study 3 was in three parts. The main aim of part 1 was to examine the use of the SAINT in practice and to inform a number of areas for subsequent studies including recruitment, attrition, issues relating to its administration and tolerance of the intervention. In part 1 the baseline (A) and intervention (B) phases were repeated and lasted in total 16 weeks A-four weeks, B- four weeks, A- four weeks and B- four

weeks. The GDS-LD, GAS-ID and SAINT feelings were recorded across all phases to examine change between phases.

Part 2 examined the SAINT in practice over a longer period of 22 weeks. The initial baseline phase was extended to A-seven weeks, B-five weeks, A- five weeks and B-five weeks. The extended baseline offered an opportunity to observe the target behaviour over a longer period and to ensure it is stable prior to any intervention. The second part of the study contained one new participant who acted as a control over the extended period. The aim was to replicate positive findings in at least one and up to three previous participants who had achieved decreased scores in the both intervention periods in part 1, across all three measures. This is standard practice in SCED and is designed to see if positive outcomes can be repeated and are less likely to be by chance. Unlike other methods where familiarisation of the intervention may increase scores, SCED also withdraws the treatment prior to a subsequent intervention phase with the expectation that scores will return to baseline. Therefore a break of 6 months prior to joining part 2 was enforced to limit familiarisation.

Part 3 of the study collated user feedback on the SAINT and aimed to inform any necessary amendment and to evaluate outcomes from user experiences using qualitative methods.

5.3.2 Recruitment and Attrition (Part 1 and 2)

Part 1: Of the 22 people that were identified and met eligibility criteria, 7 were withdrawn by clinical teams or those supporting them either before or in the first few weeks of baseline data collection. Although the recruits had been cleared to participate by the clinical teams, there were belated concerns of the potential effects

on current treatment the project might have. Of the 15 left, all completed the SAINT over 1 or more baseline and intervention *male* = 7, (46.7%) (*M* = 44.3 years old, *SD* 19.47, range 18-68), *female*=8, (53.3%), (*M*= 31.38, *SD* 9.9, range 21-46). Twelve participants completed all four phases.

Part 2: Three people were recruited to part 2, all of whom completed the four phases (A-B-A-B). All were *male*, aged between 46-58 years, *M*=50; *SD* 6.93. For recruitment breakdown see Figure 11.

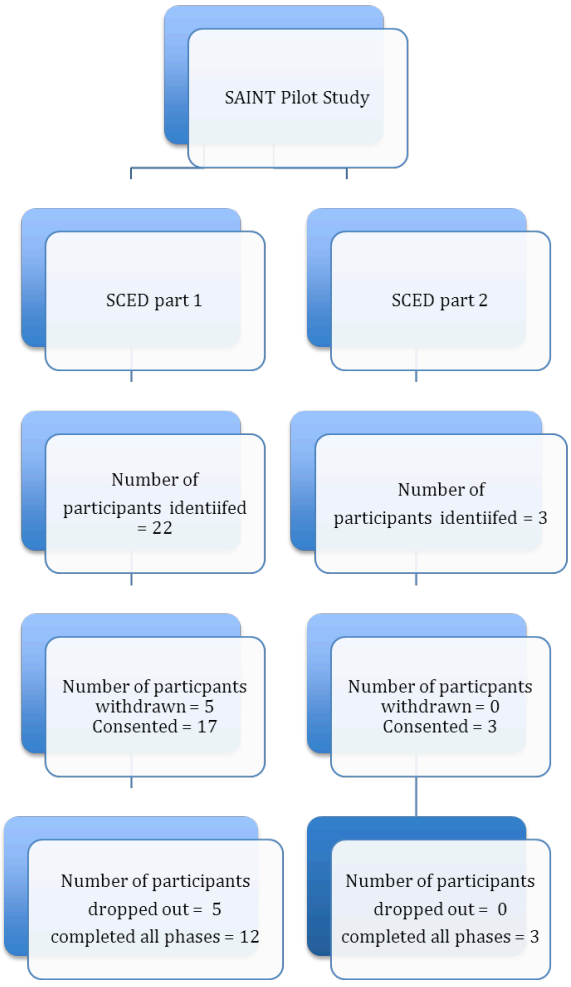

Figure 11 Study 3 Recruitment

For the Qualitative sub study 16 participants who expressed an interest in giving feedback were approached to participate in the semi structured interviews. Of these six declined leaving nine participants.

Recruits to the final study comprised participants who had previously declared an interest in participating during the reliability and validity stage. As part of the consenting process, participants were asked the level of support they would expect between sessions from staff and/or carers. All of the participants consented said that they had access to support should they require it.

Given the increased contact with participants in study 3, the local NHS and University safeguarding procedures were again considered. Participants were told that any information they gave which gave the researcher concern for the persons safety or the safety of others would need to be reported e.g., suicidal thoughts, crimes being revealed or worries for the persons safety. During the study this was necessary on two occasions.

1. One participant disclosed they had met a 'new friend' who they were giving money to when they met. This raised concerns that they were being taken advantage of and having monies stolen from them. (The staff at the house was informed and this became a police matter. Following investigation it was established that the participant was giving away there benefits for what they saw as friendship. The police spoke to the person receiving the money with no further action taken due to insufficient evidence that a crime had been committed.)

2. A participant with a history of serious mental illness became increasingly paranoid and was having difficulty interpreting events around him and maintaining reality during a session. The session was interrupted and the participant was taken to see their CPN. They revealed that his medication had not been dispensed correctly and that this had coincided with the deterioration in mental state. A new prescription was dispensed following a clinical review by a psychiatrist

Participants were allocated a one or two digit number as a personal identifier. This meant that no identifiable information was used during sessions and the anonymised data were filed directly onto the study database. To maximise the likelihood of support between sessions, participants were encouraged to invite staff and/or carers to weekly meetings. In spite of this all of the participants met with the facilitator alone for the majority of sessions. Only two people were accompanied during sessions and this was in the first week to help with specific communication difficulties. One person allowed house staff to sit in with the sessions but was keen they observed rather than participated. Another person was keen to keep his time and materials relating to the SAINT private but requested his mother was kept up to date. The facilitator would ring the participant's mother following sessions with the participant listening to the conversation on speakerphone.

Feedback between sessions from participants told how they would show staff or carers the SAINT booklet following sessions. This was useful as it would provide a way of talking about and sharing how they felt. The day before appointments,

participants and/or house staff were rung to confirm whether the scheduled meeting time was still acceptable. This was necessary as often in the early weeks people forgot the exact times or were not reminded when the sessions were.

5.4 **Procedure**

The use of the SAINT GSH materials (see appendix 4) was reinforced during weekly sessions, (facilitated by a Registered Nurse), and an accompanying training guide which was designed for both participants and those supporting them (see appendix 5). The training guide included six case examples to illustrate how the SAINT should be used in a variety of situations, e.g., "when someone feels sad", "when someone has a good day" and "when to talk to someone who is angry so they can engage".

During the study a Nurse administered the GDS-LD GAS-ID and the SAINT weekly. During administration in the baseline weeks no other inquiry or conversation was made about the person's mental health. In the intervention weeks, the Nurse used the SAINT to encourage the participant to reflect on the previous week and to encourage them to build upon successes and look forward to the week. Sessions took place every 7 days, +/- 2 days to allow flexibility and choice to participants. All participants saw the Nurse weekly, regardless of whether it was for intervention or to collect baseline data. This added consistency to any results whether positive or negative as visits were consistent thorough both the baseline and intervention phases. Although support was encouraged not everyone had received support to use the SAINT in the previous week. All materials relating to the SAINT

were removed from participants during the baseline phases. The SAINT as an intervention was replaced by general conversation. This acted as a dummy variable.

5.5 Reliability and validity parts 1 and 2

SCED can be used with just one participant with studies rarely having more than ten participants. It is widely regarded that:

- One is required to demonstrate
- Between two to four is required to directly replicate (3 credible)
- Five or more to start to systematically replicate

(Freeston, 2011)

The SCED is a powerful tool where design is paramount in determining the scientific quality of any study. It allows analysis of groups of participants by characteristics e.g., by therapist, age, gender, co-morbidity, treatment response etc., to increase robustness of study

5.5.1 Rater Reliability

The inter-rater reliability of the SAINT was established on five cases with unanimous agreement of scores by three Registered Nurses (one mental health branch (EC) and two from the learning disability branch (SH and MF). The self report nature allowed raters to ask the person to decide on their answer; i.e., yes or no for the SAINT or no, sometimes, always for the GDS-LD and GAS-ID.

5.5.2 Dependent Variable

The dependant variables are depression and anxiety as measured by the GDS-LD and GAS-ID.

5.5.3 Independent Variable

The independent variables for the study were the coping strategies, gender, residence, current service provision, diagnosis, level of functioning and mental health diagnosis.

5.5.4 Experimental Control/internal Validity

Internal validity is concerned with conclusions from the data and asks the question does it reflect what is being reported. To address this issue, SCED design seeks to ensure internal validity is addressed through:

- The demonstration of experimental effect over at least 3 phases e.g., A-B-A or A-B-A-B
- By ensuring there are adequate measurement points within phases,
- Participants act as their own controls
- The relationship of mediators and moderators to the outcomes

Examples of threats to internal validity include:

- **History:** Does another current event effect the change in the dependent variable?
- **Maturation**: Are changes in the dependent variable due to developmental issues?

- **Statistical regression:** Do subjects come from low or high performing groups?
- **Selection:** Have the subjects been self-selected into experimental and control groups, which could affect the dependent variable?
- **Experimental Mortality**: Have some subjects dropped out? How does this affect the results?
- **Testing**: Did the pre-test affect the scores on the post-test?
- **Instrumentation:** Did the measurement method change during the research?
- **Design contamination**: Did the control group find out about the experimental treatment?
- **Reactive effects of experimental arrangements**: Need to replicate the findings in other locations and other time periods.

Campbell & Stanley (1966)

The role of moderators is to examine for who treatment is more or less effective for, whereas mediators identify and examine what the effective elements of treatment are (Maric, Wiers & Prins, 2012) for example in a GSH study mediators that could be put forward for analysis are the GSH materials used, facilitation style or use of specific cognitive behavioural techniques. SCED's can utilise the ongoing assessment of participants to examine the relationship between the chosen mediator and outcome. The design can also be used to establish mediators by looking between phases at the introduction and withdrawal of variables such as a new intervention. In terms of external validity the SCED needs to be repeated in different settings,

replicated and have enough participants to be able to establish an effect. The threats to validity that need to considered are:

- To ensure that results are not due to other incidents e.g., life events, ecological fallacy i.e., the person acts like the majority of the population
- That responses are not due to acquiescence or suggestibility
- That the sample is not representative of the population studied or the intervention is not realistically implemented

In this study the two baseline phases were used to demonstrate experimental effect within and between each individual data series. Experimental control was achieved through a) the introduction and reversal of the independent variable, b) staggered introduction of the independent variable over two time points (see Horner, Carr, Halle*, et al*, 2005, p168). Part 2 of the study was designed to see if positive findings from part 1 could be replicated.

To maintain internal consistency of the study any queries about any aspect of the study were addressed to the PI. Off site support from the PI was made available following training. Additionally each participant and those supporting them were trained in the use the SAINT. A mobile contact number for the PI was given to all participants with the SAINT supplied with the training manual.

5.5.5 External Validity

External validity conversely is concerned with the generalisability of study findings to other groups and settings. Threats to external validity include:

- How the sample is selected e.g., are they randomised
- Do they have previous exposure to the intervention
- Involvement of multiple treatments

This means studies or concepts need to be tried in populations not previously targeted. In this case the use of GSH in people with intellectual disability. The external validity was also strengthened for this study by the recruitment of participants from a range of clinical and residential settings, across gender and ethnic groups and with differing levels of functioning within the target population to increase generalisability across intellectual disability groups.

5.5.6 Social Validity

The study is socially important and addresses the issue of equity of treatment for people with intellectual disability. In particular having access to the full range of psychological therapies that promote positive mental health and which are used as early intervention strategies. Although GSH is an established treatment there is no evidence if it works for people with intellectual disability.

5.5.7 Data and Analysis

Visual analysis is the predominant method of data analysis SCED and was used in this study. The sampling and design of this current study means traditional statistical analysis is limited.

5.5.8 Interpreting visual analysis

Visual analysis is the traditional method for analysing SCED. It involves examination both within and between data patterns in order to explore the likelihood of a causal relationship. When analysing data six factors can be considered (1) level,

(2) trend, (3) variability, (4) overlap, (5) immediacy of the effect, and (6) consistency of data patterns across similar phases, (Barlow, Nock & Hersen, 2009; Fisher, Kelley & Lomas, 2003; Kazdin, 1982; Kennedy, 2005; Kratochwill, Hitchcock, Horner*, et al*, 2010; Morgan & R., 2009; Parsonson & Baer, 1978). Examples of a good outcome from each of the six factors are reproduced below (see Kratochwill, Hitchcock, Horner*, et al*, 2010). The formal standards expected for the presentation of chart data have been followed (see Parsonson & Baer, 1978; Dixon, Jackson, Small*, et al* 2009).

5.5.9 Level

Level refers to the mean score for the data within a phase. In the example below, the horizontal line represents the interval between data collection points by time e.g., minutes hours, days week and the vertical line represents the score on the scale used e.g., GDS-LD. The table below shows a decrease in mean scores from the initial baseline (A1) to the first intervention phase (B1). This follows a return to baseline at A2 before a decreased mean score in the final intervention phase (B2), see Figure 12.

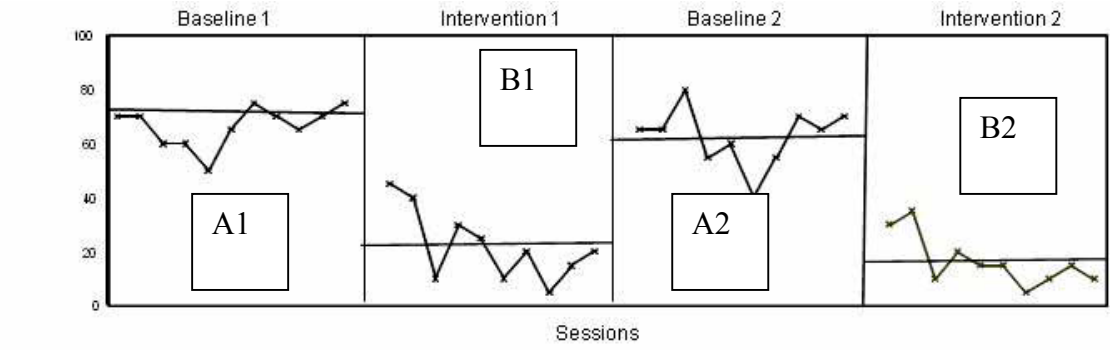

Figure 12 Level

5.5.10 Trend

Trend refers to the slope of the best fitting straight line for the data within a phase. The table below shows the scoring trend from the initial baseline (A1), which rises prior to the first intervention phase (B1). In (B1) the trend line slopes downward as the intervention is introduced. There is no carry over effect as we see a return to baseline at A2 before a descending slope in the final intervention phase (B2) as the intervention is reintroduced, see Figure 13.

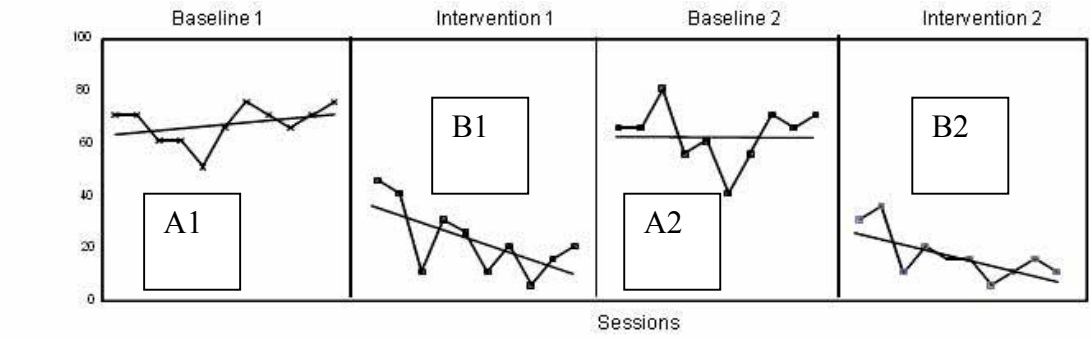

Figure 13 Trend

5.5.11 Variability

Variability refers to the range or standard deviation of data about the best fitting straight line. The table below shows an upward slope in the initial baseline (A1) The first intervention phase (B1) sees the slope descend with all scores lower in the this phase. Although in A2 the there is still a downward slope it is at a higher point than in B1 and continues to slope downward as scores improve in the final intervention phase (B2), see Figure 14.

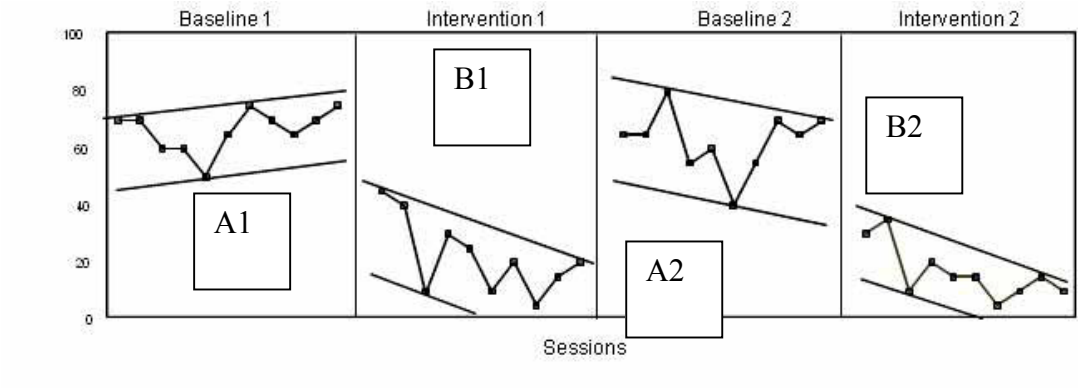

Figure 14 Variability

5.5.12 Immediacy

"Immediacy of the effect" refers to the change in level between the last three data points in one phase and the first three data points of the next. The table below shows how quickly from the initial baseline (A1) to the first intervention phase (B1) do scores decrease to demonstrate effect of the intervention. In both intervention phases (B1 and B2), we see a sharp decrease in scores as soon as the intervention is introduced. Baseline 2 (A2) also shows a downward trend see Figure 15.

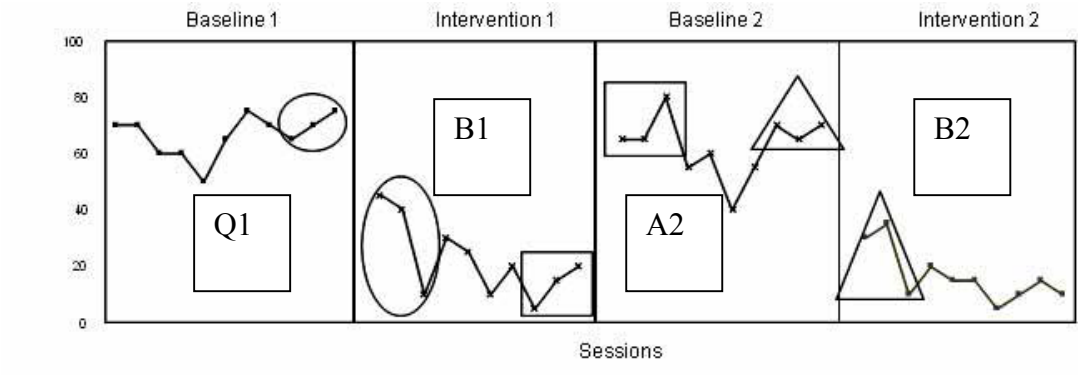

Figure 15 Immediacy

5.5.13 Overlap

Overlap refers to the proportion of data from one phase that overlaps with data from the previous phase. The table below shows no overlap from the initial baseline (A1)

to the first intervention phase (B1) and A2 and B2. There is an overlap during one data point between B1 and A2, but overall it can be clearly seen that there is a clear reduction during both B1 and B2 from their corresponding baseline phases A1 and A2, see Figure 16.

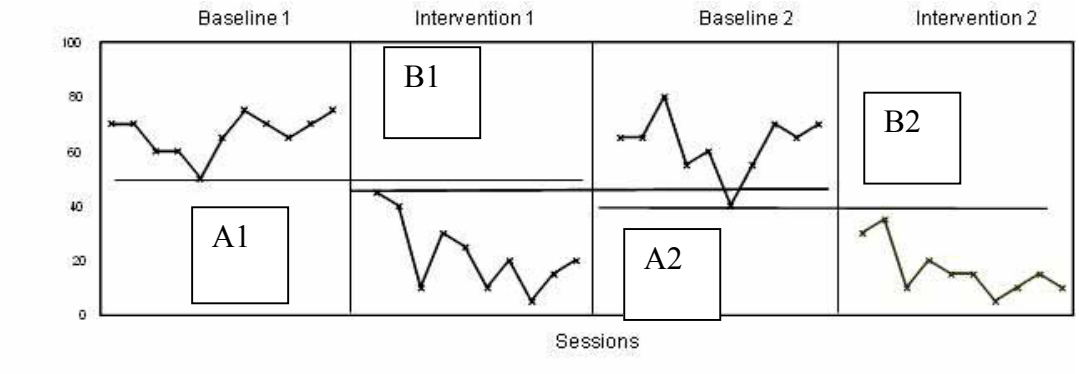

Figure 16 Overlap

5.5.14 Consistency

"Consistency of data in similar phases" involves looking at data within the same phases (i.e., all "baseline" phases; all "intervention" phases) and examining the extent to which there is consistency in the data patterns from phases with the same conditions. The table below how consistency is measured. Rather than looking for a slope or trend, consistency examines how compact the data is and if that pattern can be seen over the baseline and intervention phases from the initial baseline (A1) we see a similar pattern at A2 suggesting good baseline consistency. This is repeated in the first intervention phase B1 and carries on to B2, see Figure 17.

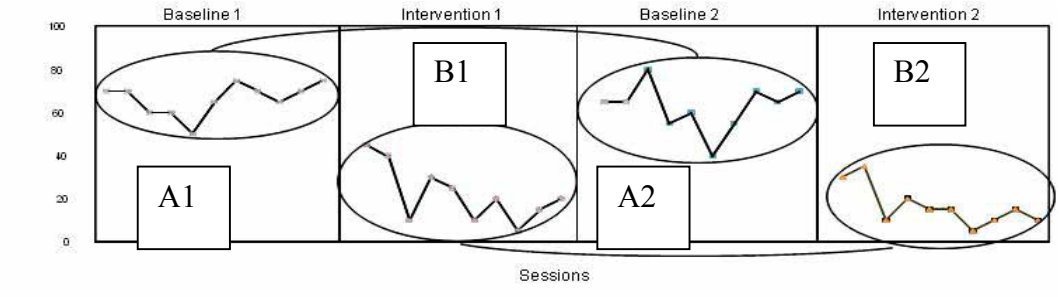

Figure 17 Consistency

5.6 Quality standards

5.6.1 Part 1

The quality standard framework used in part 1 (Carr, Halle*, et a,l* 2005) was supplemented by additional standards (Kratechwill, Hitchock, Horner et al 2010), in part 2, which were published midway through part 1 of the study, see Table 11

Table 11 Quality Standards

Horner et al 2005 Quality Standards	**SAINT Met/Unmet**
Description of Participants and Setting to allow precision to replicate the study • Participants are described in detail to allow replication • The process for selecting participants is described in detail • Critical features of the physical setting are described	Met
Dependent Variable • Dependent variables are described with "operational precision". • Each dependent variable is measured so it can be quantified • Measurement of the dependent variable is valid and described with replicable precision • Dependent variables are measured repeatedly over time. • Data are collected on the reliability or inter observer agreement associated with each dependant variable, and inter observer agreement (lOA) levels meet minimal standards {e.g., lOA = 80%; Kappa = 60%).	Met Inter observer agreement was completed in 5 cases as self report measures were used rather than observer reported scales. Complete agreement was reached given yes/no and sometimes always never ratings
Independent Variable Independent variable is described with replicable precision. • Independent variable is systematically manipulated and under the control of the experimenter. • Overt measurement of the fidelity of implementation for the	Met

Horner et al 2005 Quality Standards	**SAINT Met/Unmet**
independent variable is highly desirable. • The majority of single-subject research studies will include a baseline phase provides repeated measurement of a dependent variable and establishes a pattern of responding that can be used to predict the pattern of future performance, if introduction or manipulation of the independent variable did not occur. • • Baseline conditions are described with replicable precision.	
Experimental Control/internal Validity • The design provides at least three demonstrations of experimental effect at three different points in time. • The design controls for common threats to internal validity (e.g., permits elimination of rival hypotheses). • The results document a pattern that demonstrates experimental control.	Met 2 cases replicated positive results
External Validity • Experimental effects are replicated across participants, settings, or materials to establish external validity.	Met The SAINT was used across settings e.g., inpatient and residential settings
Social Validity • The dependent variable is socially important. • The magnitude of change in the dependent variable resulting from the intervention is socially important. • Implementation of the independent variable is practical and cost effective. • Social validity is enhanced by implementation of the independent variable over extended time periods, by typical intervention agents, in typical physical and social contexts.	Met Depression is a social and economic burden and this type of treatment is part of current NICE guidelines
Additional standards followed part 2 for 3 cases (Kratchowill et al 2010)	
• To demonstrate an effect, the phase must have a minimum of three data points. • To Meet Standards a reversal /withdrawal (e.g., ABAB) design must have a minimum of four phases per case with at least 5 data points per phase. • To Meet Standards with Reservations a reversal /withdrawal (e.g., ABAB) design must have a minimum of four phases per case with at least 3 data points per phase. Any phases based on fewer than three data points cannot be used to demonstrate existence or lack of an effect.	Met Additional data points and an extended baseline were added to part 2 of the third study

5.7 Results Study 3

The results are presented in two parts both using an ABAB design. Part one examined the results of the 15 cases over 16 weeks and was designed to test recruitment, and to begin to examine the characteristics of those who appeared to benefit from the SAINT.

The aim of part 2 was to replicate positive effects and to examine the intervention over a longer time period of 22 weeks.

All six factors were considered during visual analysis, trend, variability, overlap, immediacy and consistency. The most consistent indicator of change and easiest to detect visually was the mean or "level" and the median to mitigate for any outliers and these are shown on the SCED charts for illustrative purposes. The full data set with all the six factors graphed individually has been put on an accompanying Compact Disc (CD) and contains in excess of 350 SCED graphs, along with individual weekly scores for the SAINT, GDS-LD and GAS-ID for both baseline and intervention phases for all six factors.

5.7.1 Part 1 Characteristics of the Sample

Of the 15 participants, 12 completed all four phases ABAB, one completed three phases ABA and two completed two phases AB. The main characteristics of the sample related to setting and mental health are described in Table 12.

Table 12 Participants 1-15

ID. No.	Residence	Sex	Depression	Autism Spectrum Disorders	Psychosis	Level of Intellectual Disability
1	Community	M	Yes	No	No	Mild
2	Community	F	Yes	Yes	No	Moderate
3	Community	F	No	No	No	Moderate
4	Community	M	No	No	No	Moderate
5	Community	M	Yes	Yes	No	Moderate
6	In-Patient	M	No	Yes	Yes	Mild
7	Community	M	Yes	No	No	Mild
8	Community	M	Yes	No	No	Mild
9	Community	M	No	No	Yes	Mild
10	In-Patient	M	No	No	Yes	Mild
11	In-Patient	F	No	No	Yes	Mild
12	Community	F	Yes	No	No	Mild
13	In-Patient	F	No	No	Yes	Mild
14	Community	F	No	Yes	Yes	Mild
15	In-patient	F	No	No	No	Mild

5.7.2 Guide to charts and tables

The SCED diagram below is designed to assist understanding to interpret the SCED charts that follow, see Figure 18. The y-axis denotes score on the stared measure whilst the X-axis is the number of weeks and refers to all tables and graphs in this section.

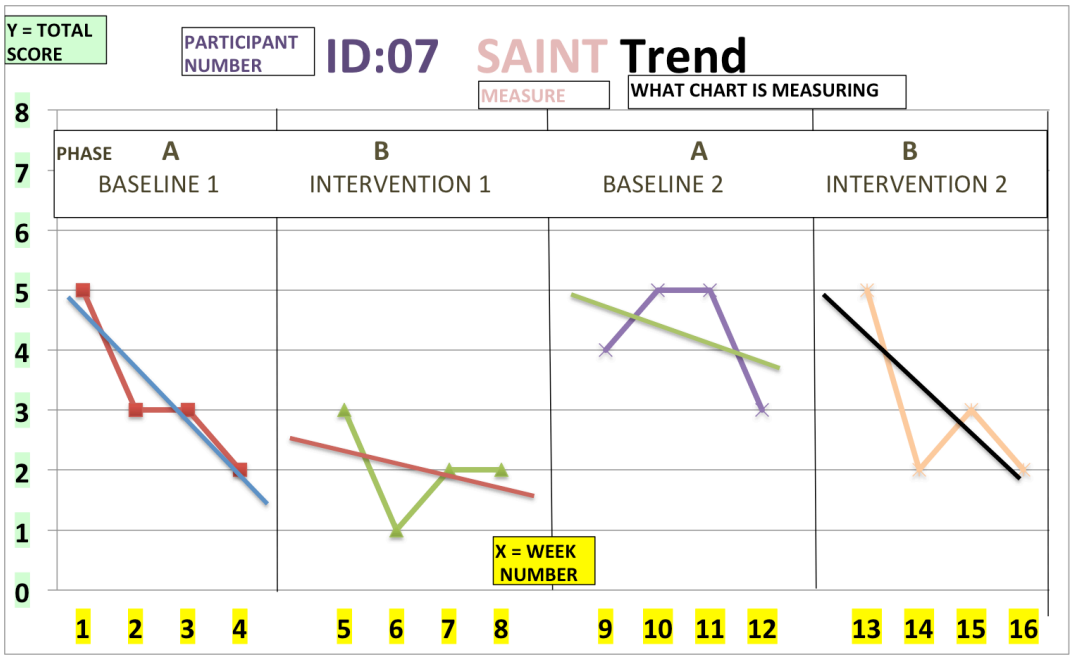

Figure 18 Key to interpret SCED charts

5.8 Part 1

5.8.1 Results Grading

Results are presented and graded as follows:

1. Participants with a decrease in mean scores in both intervention phases (B1 and B2) across all measures
2. Participants with decreased mean scores in 1-2 measures in both intervention phases (B1 and B2)
3. Participants with other evidence of a positive effect
4. Participants who fail to demonstrate a positive effect

Participants with a completion rate of less than 50% in any one phase were excluded from the study. This criteria is stricter than other GSH studies that have reported results on participants attending one to two sessions with the facilitator (Williams, Wilson, Morrison, *et al,* 2013). The number of completed sessions is given in the case summaries below.

5.9 Participants with a decrease in mean scores in both intervention phases across all measures [1]

5.9.1 Participant 07

QD is a 46-year-old male who has a mild intellectual disability and history of depression. Early in the year prior to the study his wife died and during the study his aunt died, leaving him with no family. Other life events worthy of mention at this time included moving from 24-hour care supported living to a more independent outreach service. QD leads an active life and advocates for other people with intellectual disability in both in meetings and conferences. In spite of being able to speak up there are many areas in which he still needs support, which he recognises.

QD used the SAINT during weekly visits in the intervention phases and with staff support between sessions. QD would look at it alone in spite of literacy problems having memorised parts of the book. He completed all 16 sessions and was fully engaged throughout the process.

Visual analysis indicated a positive result, and a lower mean was recorded in both intervention phases (B1 and B2) compared to the preceding baseline phases (A1 and A2) across all three measures. Mean scores at A1, B1, A2 and B2 are shown below in Table 13. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 13 ID07 weekly scores

	A	B	A	B
SAINT	3.3	**2.0**	4.2	**3.0**
GDS-LD	6.0	**4.3**	8.0	**5.0**
GAS-ID	4.8	**3.0**	5.5	**3.0**

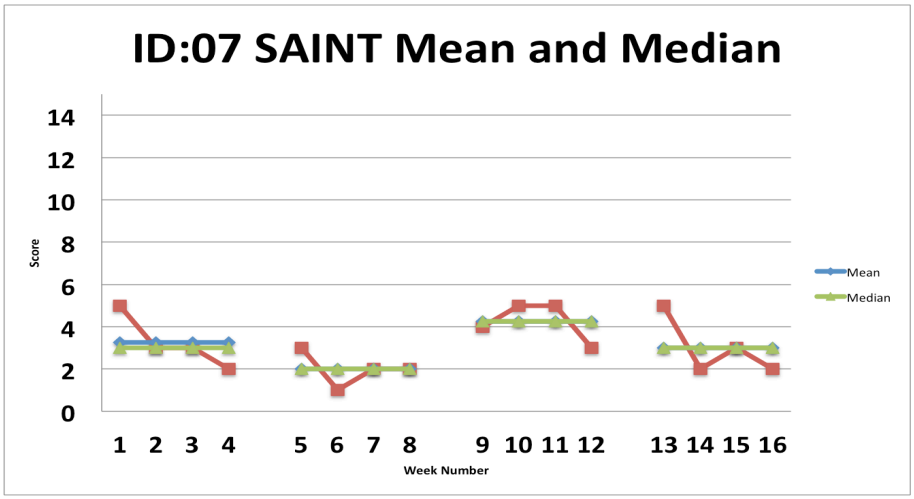

Figure 19 ID07 SAINT Mean

If the mean and/or median are not visible, results are the same. Individual scores are given in the accompanying CD. This was supported by good variability and overlap on the GAS-ID and overlap for the GDS-LD see Figure 19-22 Spikes in scoring appeared to coincide with reported events e.g., anxiety over move, bereavement etc.

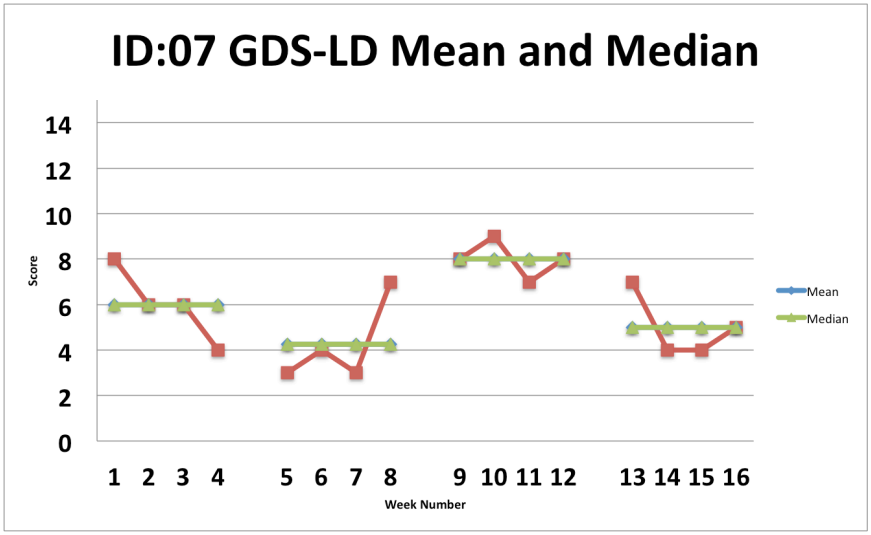

Figure 20 ID:07 GDS-LD mean

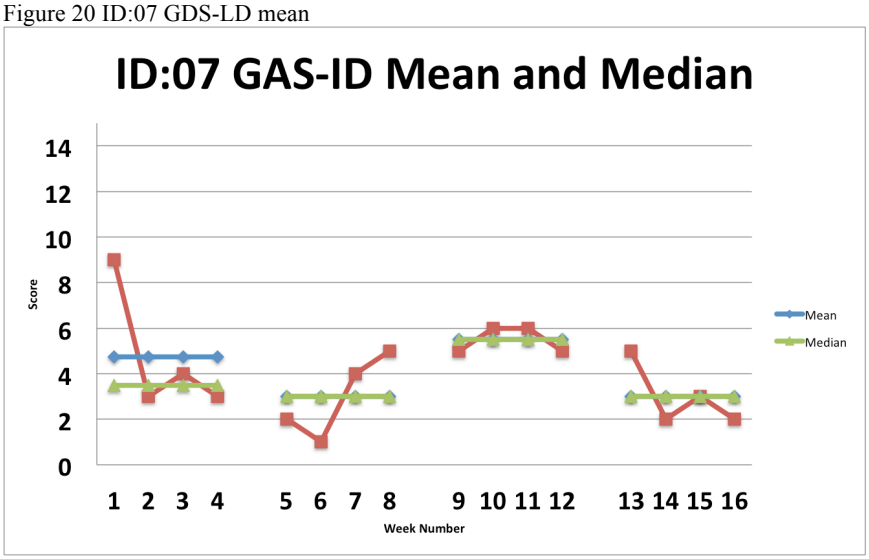

Figure 21 ID 07 GAS-ID Mean

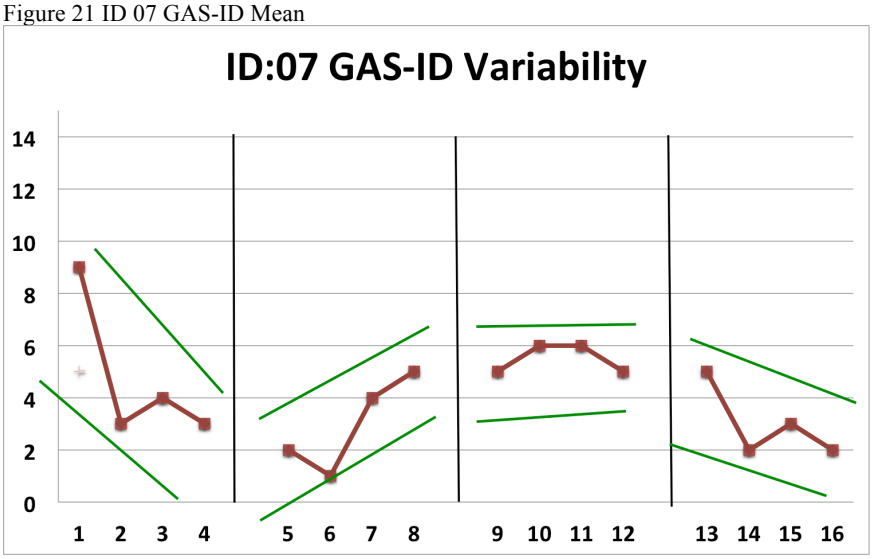

Figure 22 ID:07 GAS-ID variability

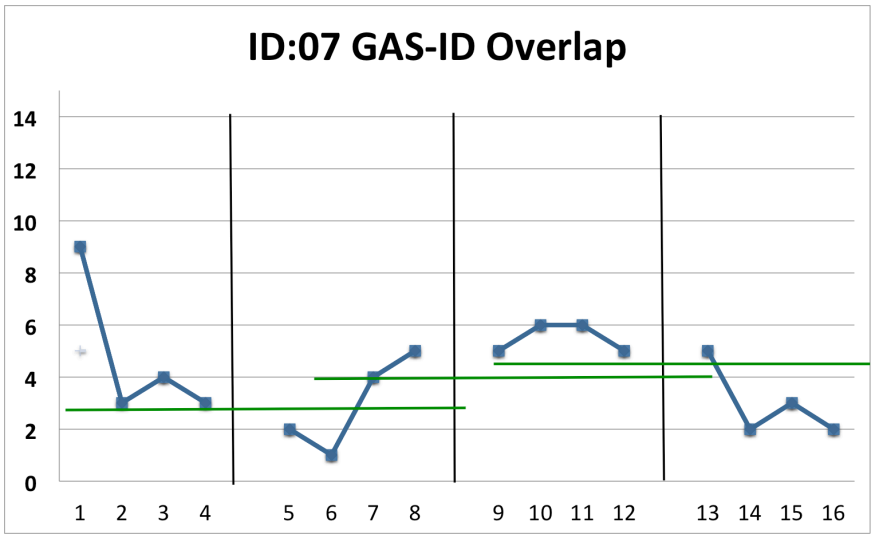

Figure 23 ID:07 GAS-ID overlap

5.9.2 Participant 04

ED is a 68-year-old male with moderate intellectual disability with no current formal mental health diagnosis. During sessions, ED appeared to want to give the "right" answers, he consistently denied anger or being in a bad mood even if his body language suggested otherwise. Evidence that ED was trying to please could be inferred by decreasing scores across the three measures and downward trend lines during the majority of phases for the GAS-ID, see Figure 24-26. Mean scores at A1, B1, A2 and B2 are shown below in Table 14. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 14 ID04 weekly scores

	A	B	A	B
SAINT	1.3	**0.7**	0.5	**0**
GDS-LD	2.5	**2.0**	0.7	**0.3**
GAS-ID	1.8	**1.7**	1.2	**0.7**

Although it seemed he enjoyed 1:1 contact it is doubtful any benefit from the book was gained apart from this. ED said he looked at the SAINT only during weekly visits, saying he could not be bothered between sessions.

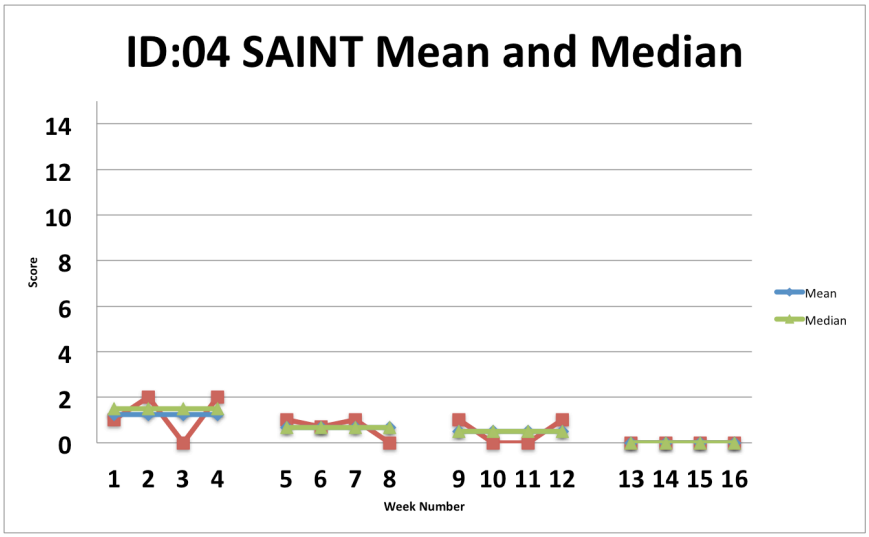

Figure 24 SAINT ID 04

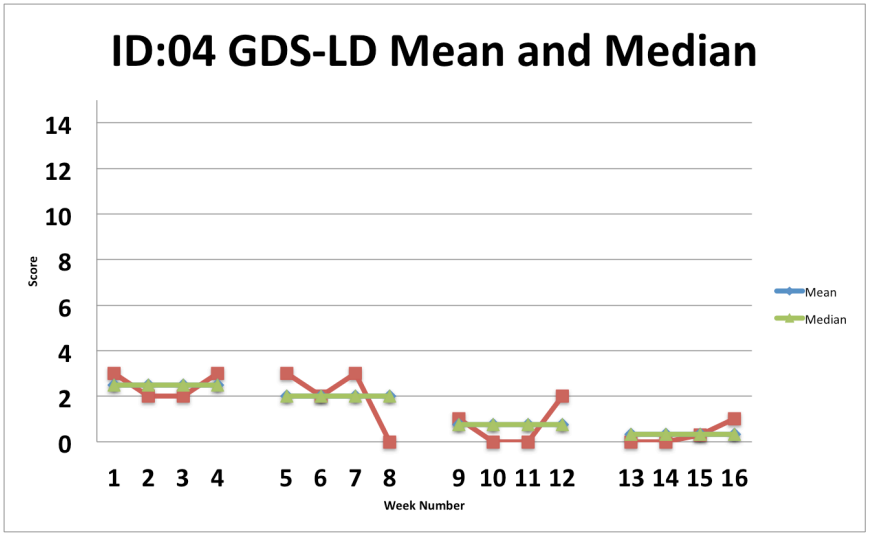

Figure 25 ID-04 GDS-LD mean

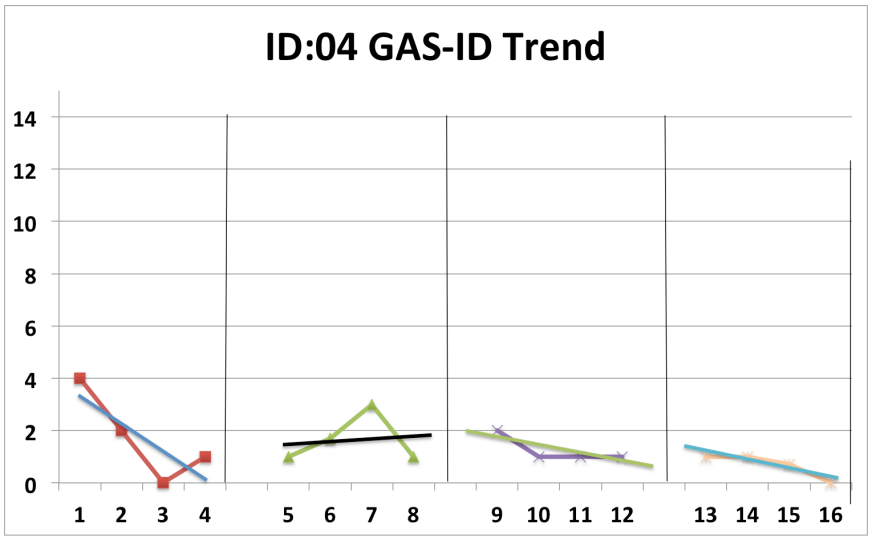

Figure 26 ID 04 GAS-ID mean

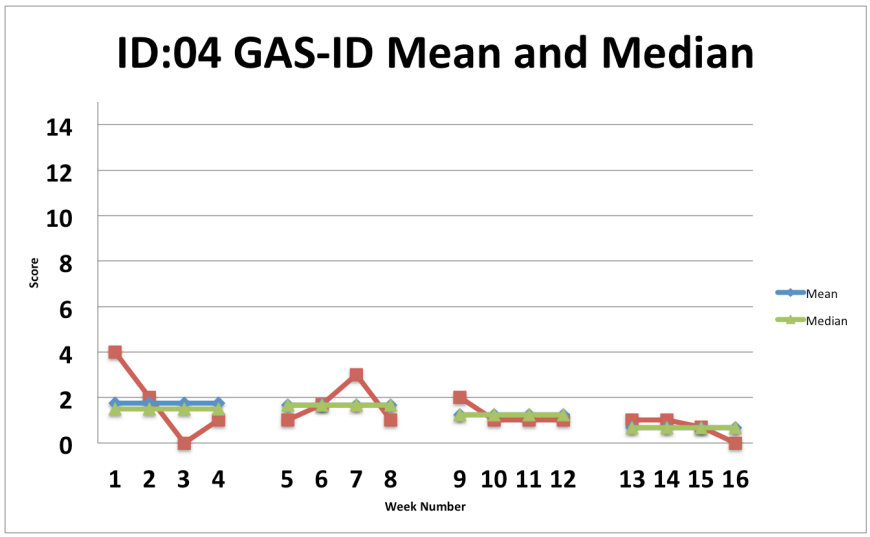

Figure 27: ID 04 GAS-ID trend

5.9.3 Participant 14

XC is a 46-year-old female with mild intellectual disability and autism, who suffered a recent psychotic episode requiring inpatient treatment. During the study, XC was often unreliable in terms of being at home for pre-arranged sessions, which often had to be rearranged. She would often blame the nurse for not visiting her even though she had gone out and made herself unavailable. In terms of support XC lives alone

with outreach support, although she says she had asked for support from staff to use the SAINT their input appeared to be sporadic at best. XC reported having looked at the SAINT from time to time between sessions but there was no detectable pattern to this. XC however did engage during the intervention sessions.

The results during intervention phases were positive in terms of decreasing means with scores increasing in the baseline phases for the GAS-ID and GDS-LD see Figure 28-29. The SAINT scores however fell consistently over the four phases. In terms of trend, immediacy and overlaps a wide variation between weeks in scores meant that there was no pattern. Mean scores at A1, B1, A2 and B2 are shown below in Table 15. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 15 ID14 weekly scores

	A	B	A	B
SAINT	2.3	**1.8**	1.0	**0.3**
GDS-LD	9.3	**5.3**	6.0	**5.5**
GAS-ID	2.7	**0.3**	3.2	**1.8**

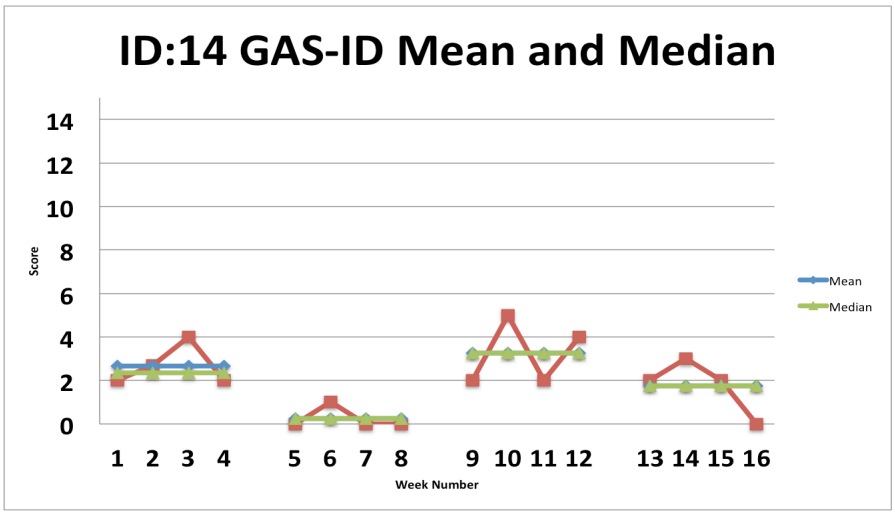

Figure 28 ID 14 GAS-ID Mean

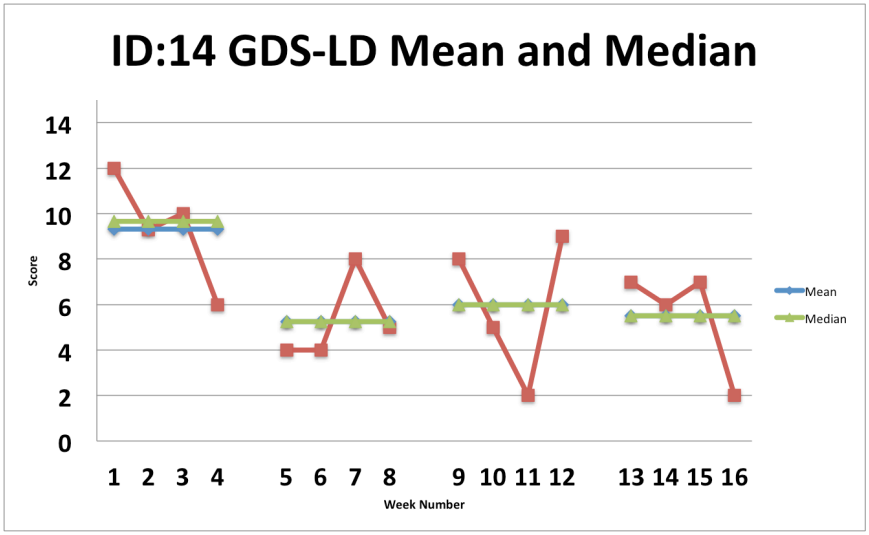

Figure 29 ID 14 GDS-LD Mean

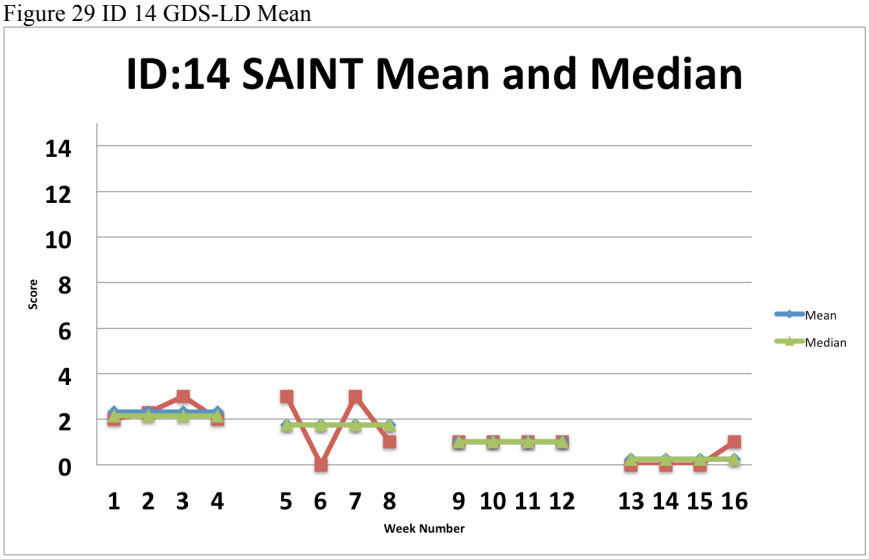

Figure 30 ID-14 SAINT Mean

5.10 Participants with decreased mean scores in 2 measures in both intervention phases [1]

5.10.1 Participant Number 02

KQ was 46-year-old female with a moderate intellectual disability and current history of depression and CB. KQ was present for 87.5% *n*=14 sessions. During weekly intervention sessions KQ would report not having used the SAINT outside of

the weekly sessions, saying that staff at the house were reluctant to offer her support to use it.

Visual analysis showed SAINT GDS-LD and GAS-ID mean scores had decreased in the experimental phases and evidence of overlap within the SAINT between phase's see Figure 31-33. Mean scores at A1, B1, A2 and B2 are shown below in Table 16. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 16 ID02 weekly scores

	A	B	A	B
SAINT	6.3	**0.5**	6	**4.5**
GDS-LD	3.8	**10.3**	10.7	**8.3**
GAS-ID	10	10	11	**8.5**

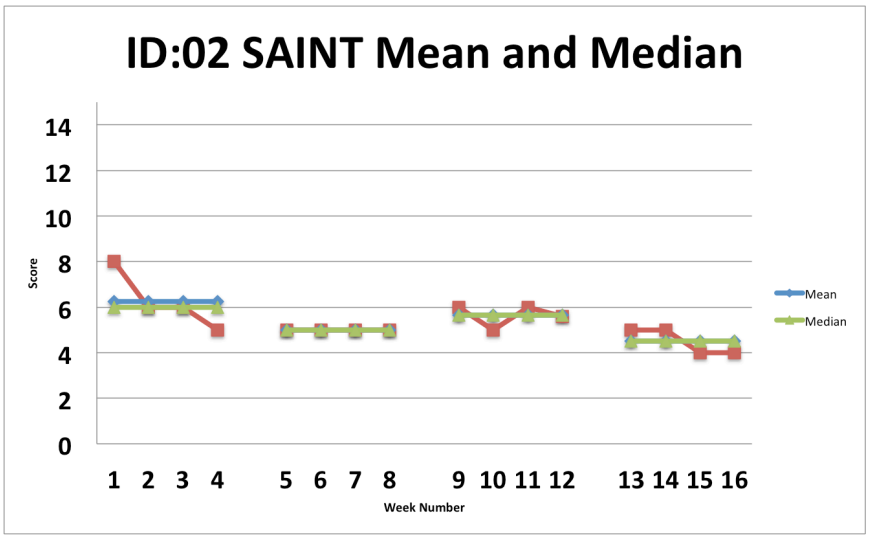

Figure 31 ID-02 SAINT mean

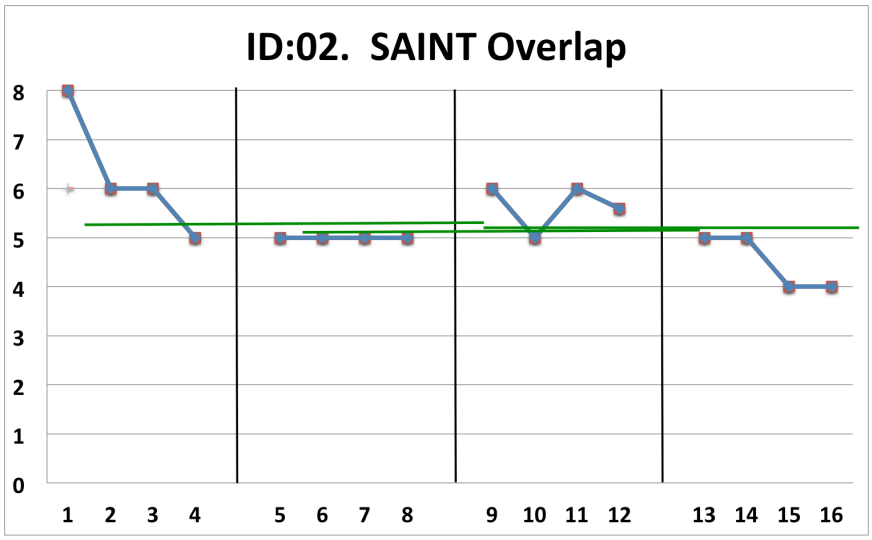

Figure 32: ID-02 SAINT overlap

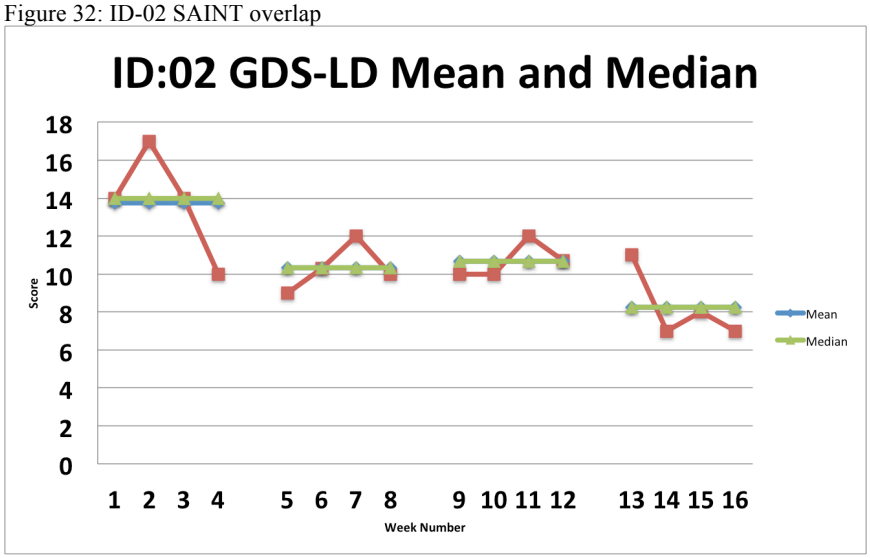

Figure 33 ID-02 GDS-LD mean

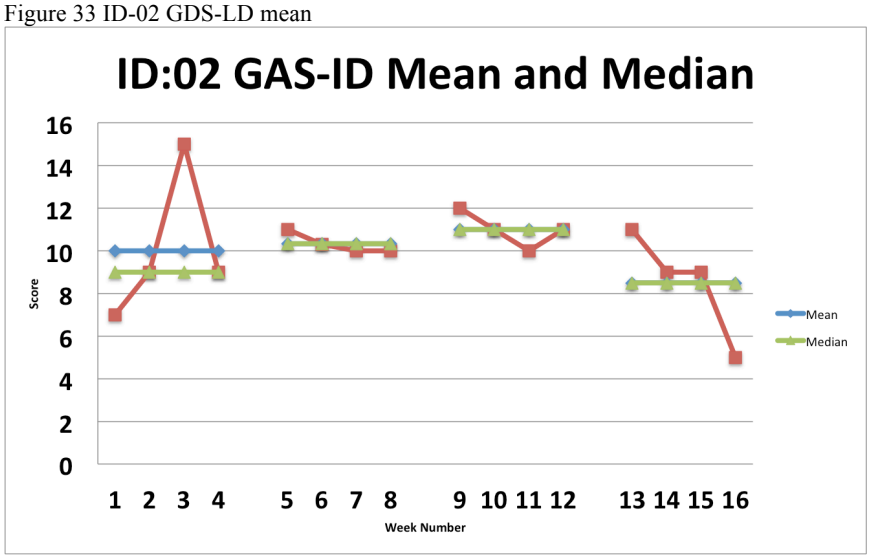

Figure 34 ID02 GAS-ID mean

There were lower means in the GDS-LD and GAS-ID intervention phases, and the GAS-ID trend line showed a reduction across B1, A2 and B2, with B2, exhibiting the steepest decline with overlap across only one data point (A2-B2), see Figure 34.

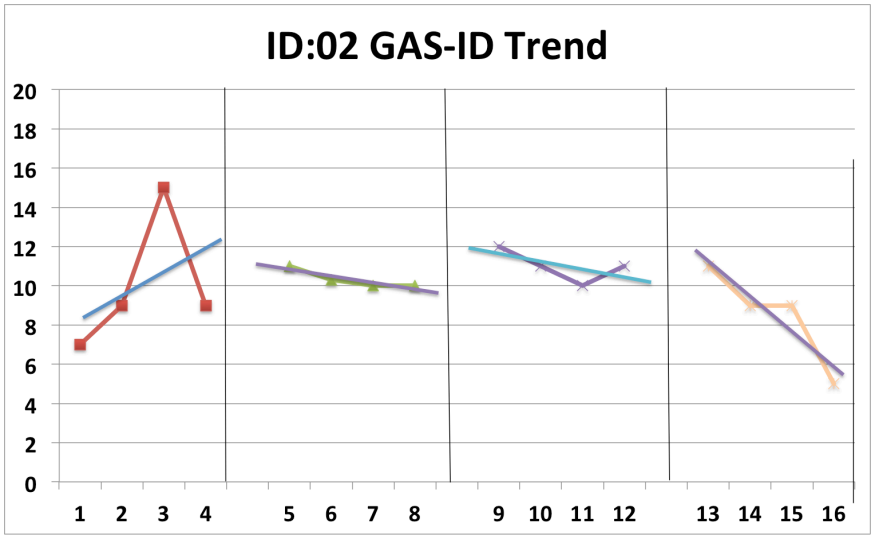

Figure 35 ID:02 GAS-ID trend

5.11 **Participant 08**

MQ is a 46-year-old male with a history of depression and anxiety he has a mild intellectual disability and subsequent diagnosis of Phenylketonuria. MQ was able to use the SAINT diary to communicate both positive and negative experiences, e.g., having a good day or being upset at leaving college, demonstrating its versatility.

MQ participated during sessions and reported to having used the book both alone and with support between sessions.

Visual analysis showed good effect with mean scores in both intervention phases showing lower results compared to baseline for the SAINT and GDS-LD. The GAS-ID only showed a decrease in the first intervention phase (B1). Mean scores at A1,

B1, A2 and B2 see Figure 36-37. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded in Table 17 below:

Table 17 ID08 weekly scores

	A	B	A	B
SAINT	1.8	**1.3**	1.7	**0.8**
GDS-LD	3.8	**1.8**	3.2	**1.5**
GAS-ID	2.5	**2.3**	1.7	2.3

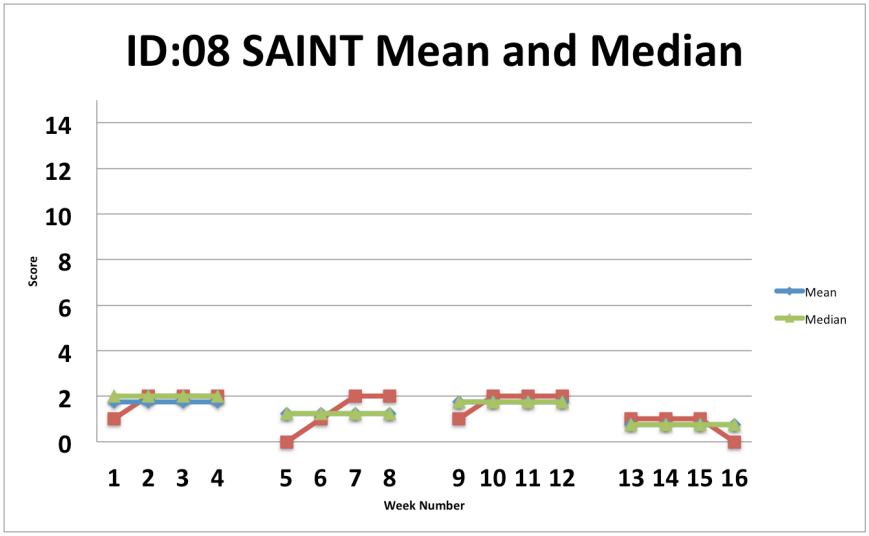

Figure 36 ID 08 SAINT mean

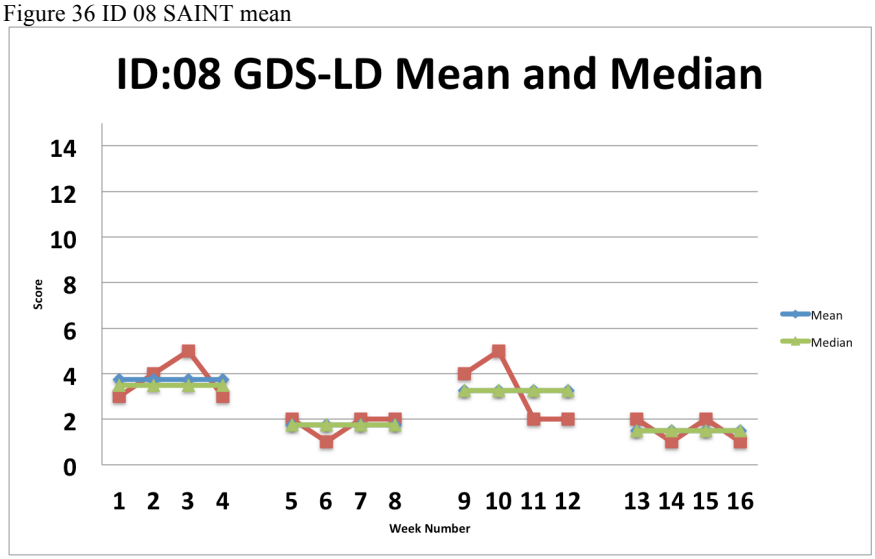

Figure 37 ID-08 GDS-LD mean

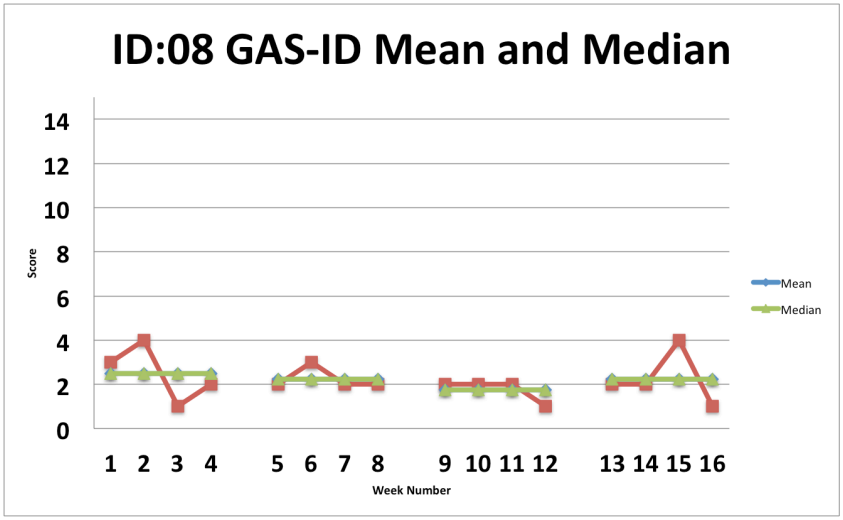

Figure 38 ID 08 GAS-ID Mean

5.11.1 Participant 03

KD is 35-year-old female with moderate intellectual disability and epilepsy. She currently lives in 24 hour supported housing with 5 other residents. KD has no formal mental health diagnosis.

For the majority of sessions it seemed KD was intent on providing the "right" response and not report any negative symptoms. With regards to coping strategies, the individual weekly sessions found that KD had some knowledge of how people might be able to help themselves. However whether coping strategies were used to any effect is unclear, as it appears there was little contact with the book between sessions.

KD used the SAINT manual well during weekly sessions, although she reported not using it in between and received no staff support. The visual analysis showed decreased mean scores in the intervention phases for the SAINT and GDS-LD, but not the GAS-ID, see Figure 39-40. Mean scores at A1, B1, A2 and B2 are shown

below in Table 18. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 18 ID03 weekly scores

	A	B	A	B
SAINT	2	**1**	1.5	**1**
GDS-LD	2.3	**0.7**	2.5	**2.3**
GAS-ID	2	2	2.5	**0**

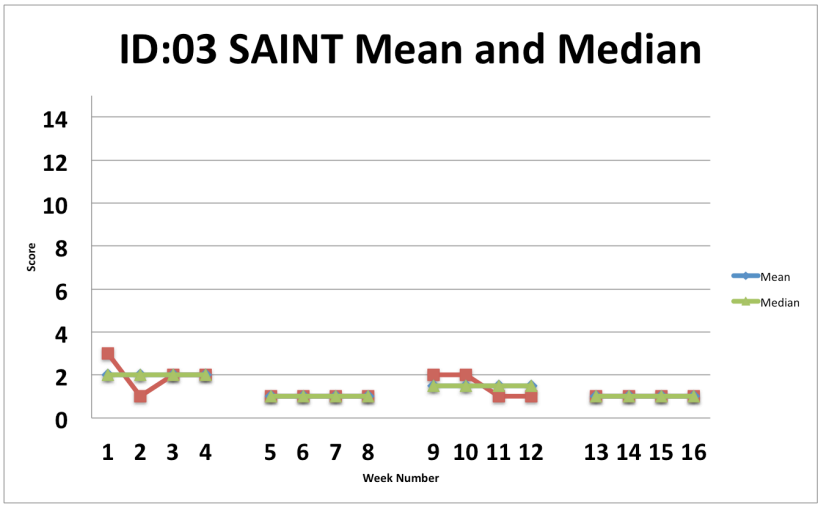

Figure 39 ID-03 SAINT mean

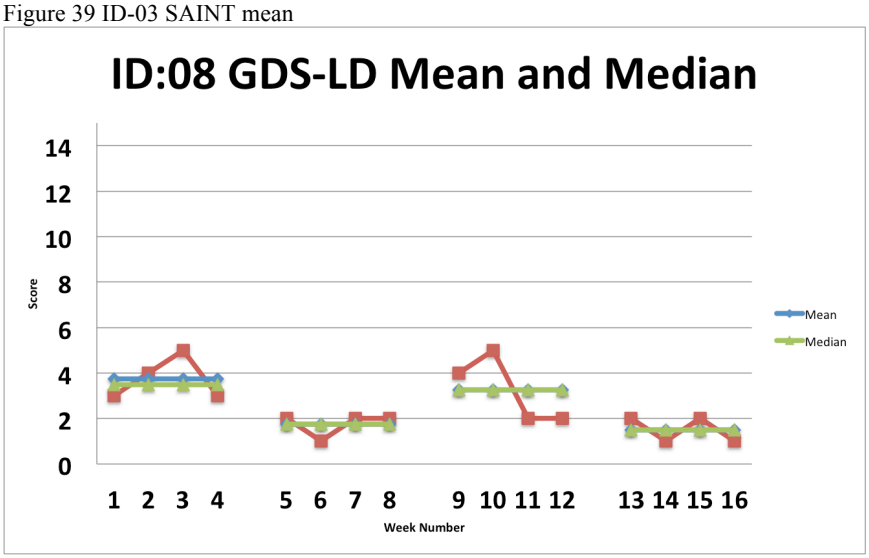

Figure 40 ID 08 GDS-LD

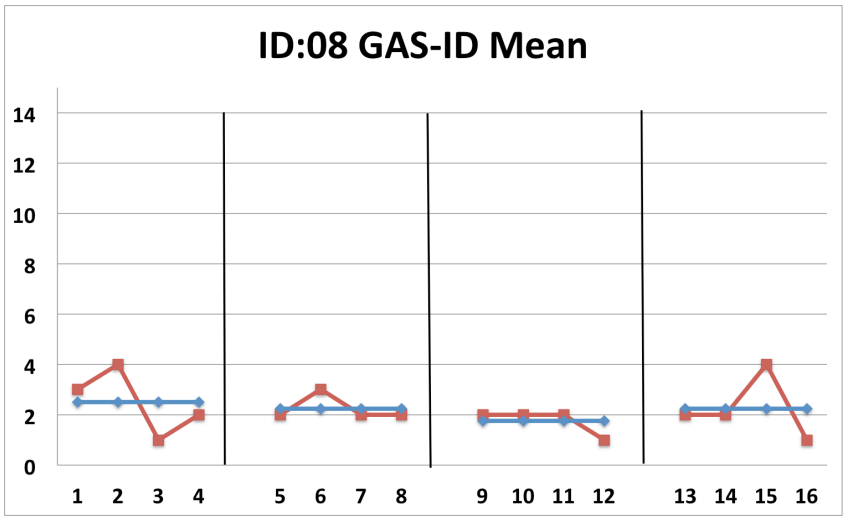

Figure 41 ID 08 GAS-ID mean

5.12 Participants with decreased mean scores in 1 measures in both intervention phases [1]

5.12.1 Participant 01

QC is a 77-year-old male with mild intellectual disability with a history of mild depression and anxiety. QC currently lives in 24 hour supported housing. Over the 16 weeks QC engaged with the SAINT during weekly visits and appeared to have a good grasp of the concept. During the intervention sessions QC was able to talk about how he felt and what thing he did to make it better. The main concern he expressed during sessions was that he wanted a friend or a girlfriend, the lack of which appeared to impact on his self-esteem. There were a number of ex staff that he missed and also the times and activities they had enjoyed which he felt no longer happened. QC said that he enjoyed the SAINT sessions and was always keen to know when the next appointment would be. His use of the booklet from his reports was poor. He did not show it to staff to help him and kept it "safe" most of the time although he reported to look at it from time to time. QC missed a number of sessions

not keeping or rearranging appointments that had been made. The house staff would not support him to remember when sessions were or to ring to rearrange.

Visual analysis see Figure 42-44, showed evidence of improvement in the intervention phases for the GDS-LD, with trend lines for the GAS-ID showing a downward trend and reduction of anxiety symptoms. Mean scores at A1, B1, A2 and B2 are shown below in Table 19. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 19 ID01 weekly scores

	A	B	A	B
SAINT	2.3	**2**	2	2.4
GDS-LD	5.5	**3.7**	5.5	**5**
GAS-ID	2.8	**2.3**	3	3

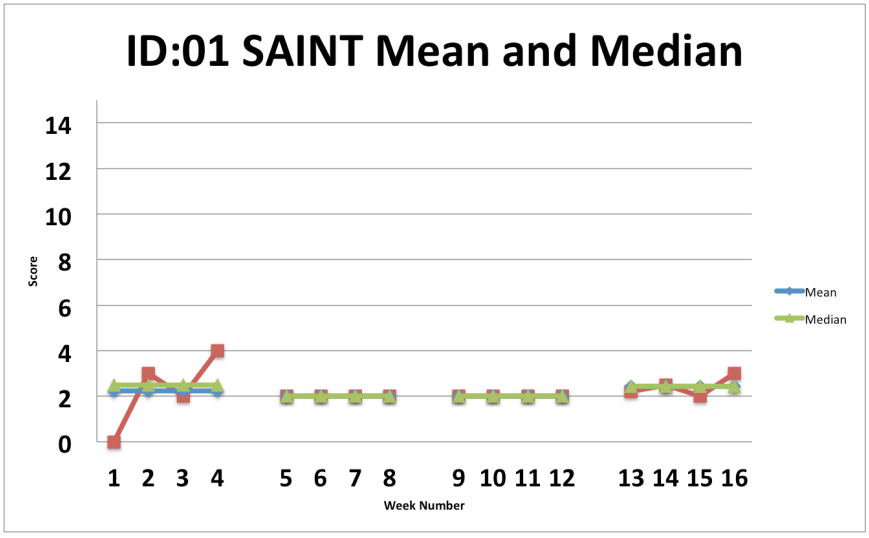

Figure 42 ID 01 SAINT Mean

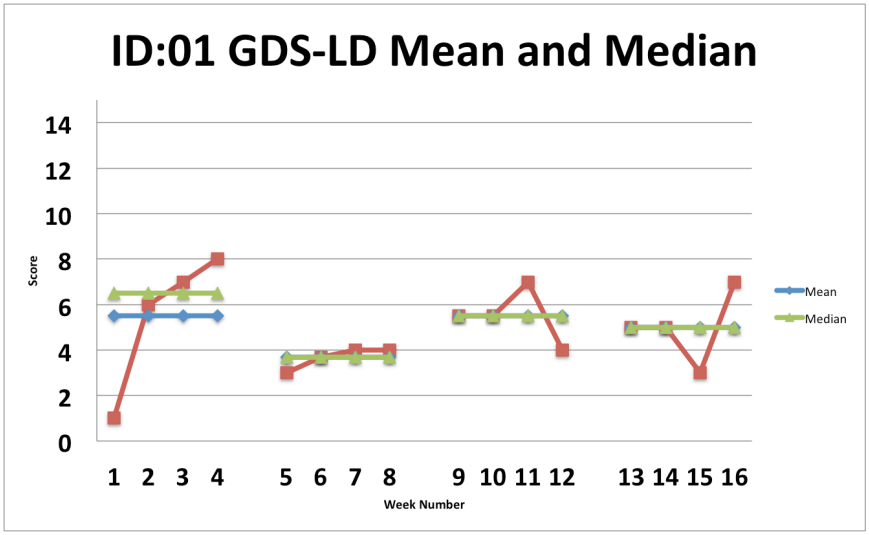

Figure 43 ID 01 GDS-LD mean

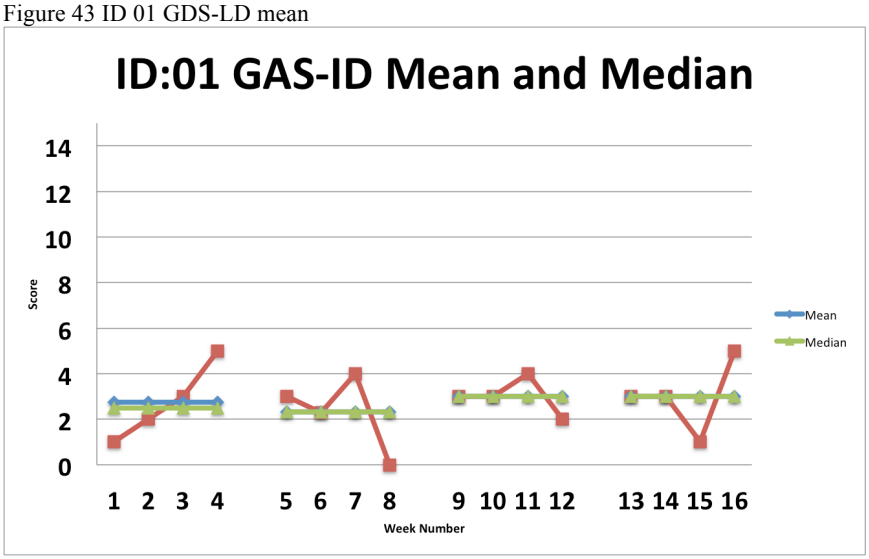

Figure 44 ID 01 GAS-ID mean

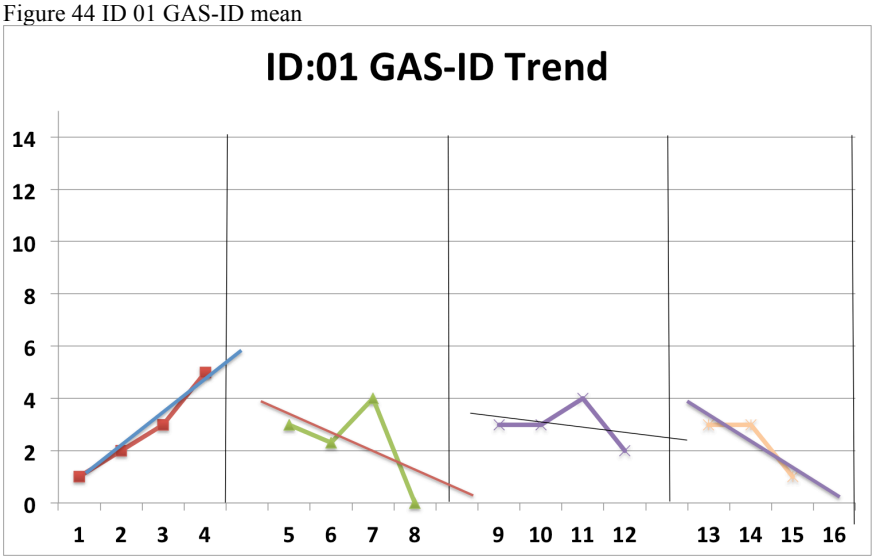

Figure 45 ID-01 GAS-ID trend

5.12.2 Participant 05

KO is a 46-year-old male with moderate intellectual disability, autism spectrum disorder (ASD) and CB. KO displayed echolalia and often needed the questions put in negative and positive formats due to suggestibility. The use of simple hand gestures e.g., thumbs up and down were used to distinguish between good and bad. KO said he used the book with staff at times and probably was the most reliable in terms of engagement of those with a moderate intellectual disability that took part. KO lived in 24 hour supported housing and reported using the SAINT outside of weekly visits with occasional staff input. There were no reports of unusual or significant incidents that may have affected weekly scores. Visual analysis proved inconclusive; whilst lower mean scores in the intervention phases using the GDS-LD, this was reversed on both the SAINT and GAS-ID. Mean scores at A1, B1, A2 and B2 see Figure 46-47. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded and shown in Table 20 below:

Table 20 ID05 weekly scores

	A	B	A	B
SAINT	3	3	2.5	3.3
GDS-LD	5.8	**5**	5.7	**5**
GAS-ID	2.8	5	1.5	3.8

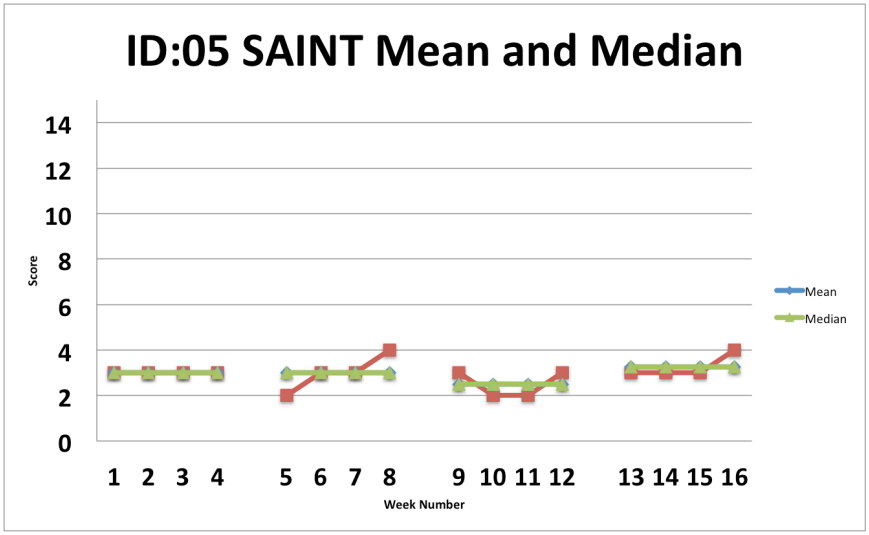

Figure 46 ID 05 SAINT Mean

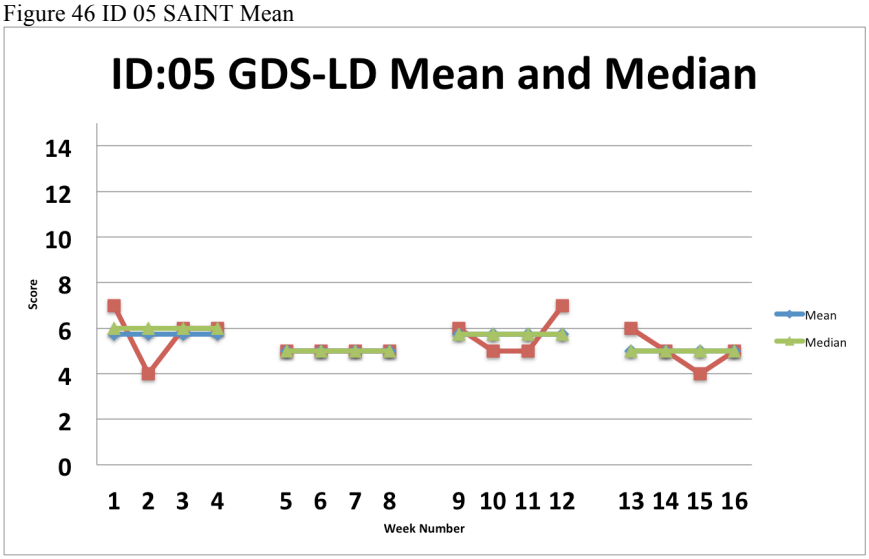

Figure 47 ID 05 GDS-LD Mean

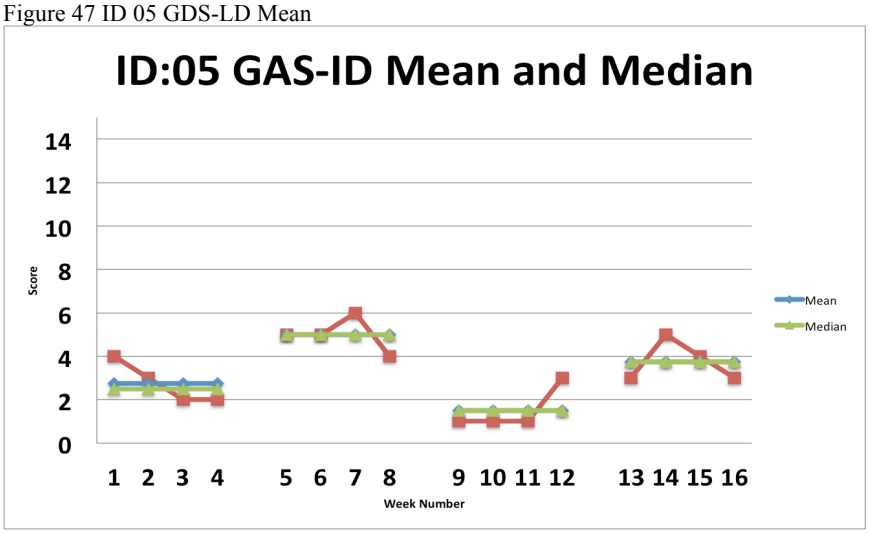

Figure 48 ID 05 GAS-ID Mean

5.12.3 Participant 13

IS is a 28-year-old female with borderline personality disorder and mild intellectual disability and is an in-patient in a national assessment and treatment unit. IS scored consistently high across all measures. A decrease in mean scores on all three measures was seen in the final phase in spite of a wide range within total scores (see Figure 49-50). The GDS-LD showed decreases in mean scores in both intervention phases. Mean scores at A1, B1, A2 and B2 are shown below. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded and shown in Table 21 below:

Table 21 ID13 weekly scores

	A	B	A	B
SAINT	4.5	6	6.3	**5**
GDS-LD	17.8	**17.3**	18	**16**
GAS-ID	9.5	11.3	10	**9.3**

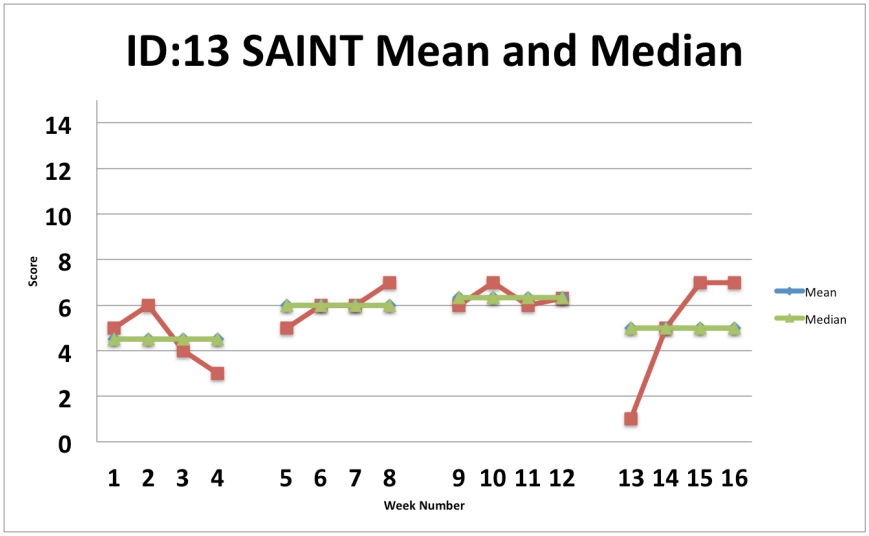

Figure 49 ID13 SAINT Mean

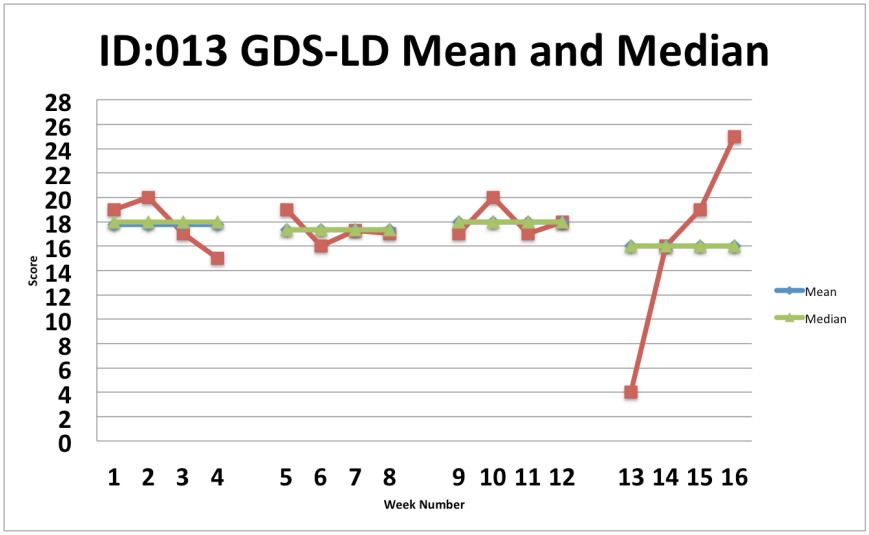

Figure 50 ID-13 GDS-LD mean

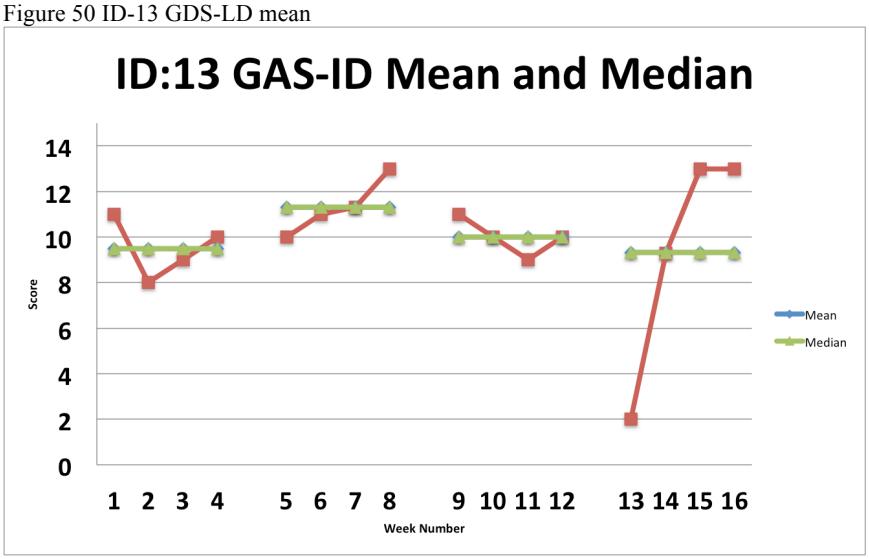

Figure 51 ID13 GAS-ID mean

5.13 Participants who fail to demonstrate a positive effect [1]

This section lists the participants who failed to demonstrate decreased scores in the intervention phase or who had dropped out before replication of the original AB had been completed.

5.13.1 Participant 06

TI is an 18-year-old male with mild intellectual disability and ASD who had been recently admitted to a national specialist assessment and treatment unit following

anti-social and violent behaviours. TI used the SAINT well and engaged in weekly sessions being regularly supported by his Primary Nurse. There was however a couple of notable events during the intervention period including an alleged sexual assault against him by another male patient and a brief return to aggressive and assaultative behaviours following a reduction in medication. This is likely to have had a negative impact on the findings and a positive result in terms of decreased scores was only seen in the first intervention phase on two of the measures SAINT and GDS-LD. The GAS-ID recorded no improvement see Figure 52-53. Mean scores at A1, B1, A2 and B2 are shown below. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded in Table 22 below:

Table 22 ID06 weekly scores

	A	B	A	B
SAINT	2	**0-8**	1	1.5
GDS-LD	3	**2.8**	2	4.5
GAS-ID	2.3	**2.8**	0	1.8

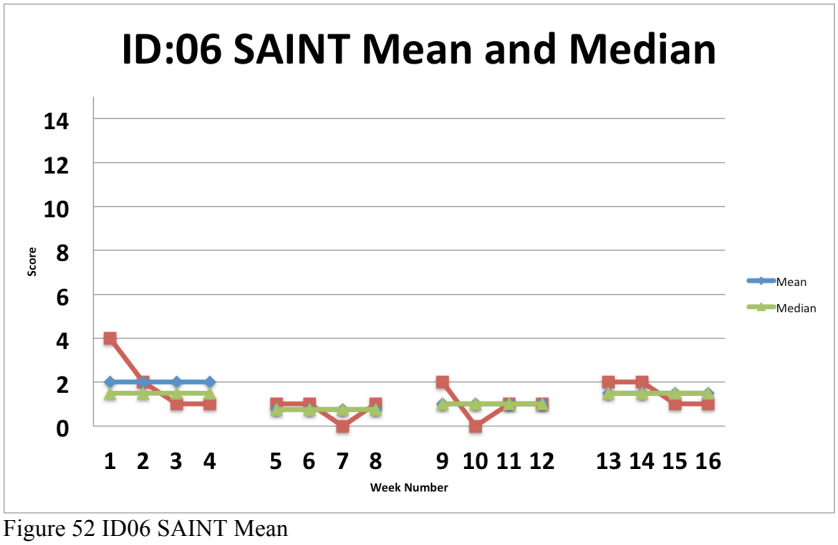

Figure 52 ID06 SAINT Mean

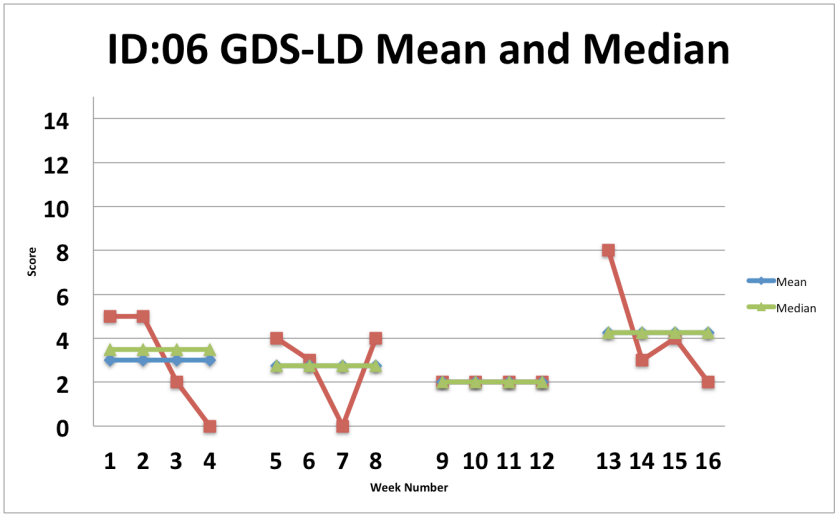

Figure 53 ID06 GDS-LD Mean

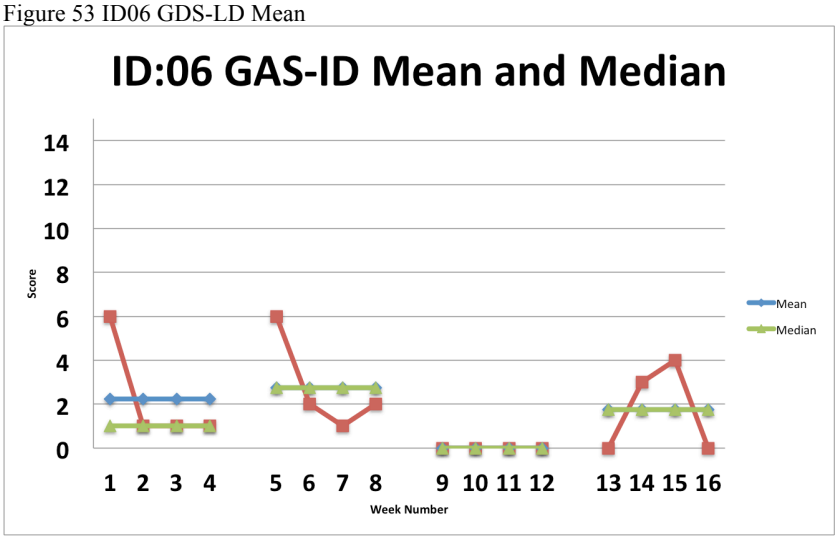

Figure 54 ID06 GAS-ID mean

5.13.2 Participant 09

OG is 26-year-old female with mild intellectual disability and a history of psychosis who had been admitted to a specialist national assessment and treatment unit. Only 2 phases were completed AB. The SAINT and GDS-LD both saw reduced scores during the intervention phase although slightly raised mean was found when using the GAS-ID (see Figure 55-56). The final AB phases were not completed due to discharge so AB was not replicated. Her scores for depression and anxiety may have been raised by the death of a younger service user on the ward during the study

period. Mean scores at (A1 and B1) are shown below. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded in Table 23 below.

Table 23 ID09 weekly scores

	A	B
SAINT	3	**2**
GDS-LD	14.7	**.8**
GAS-ID	15	15.5

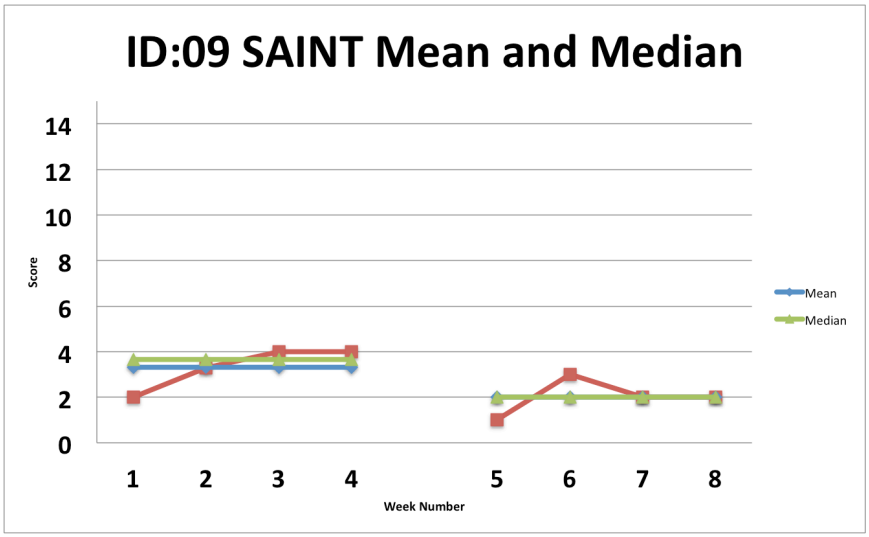

Figure 55 ID09 SAINT Mean

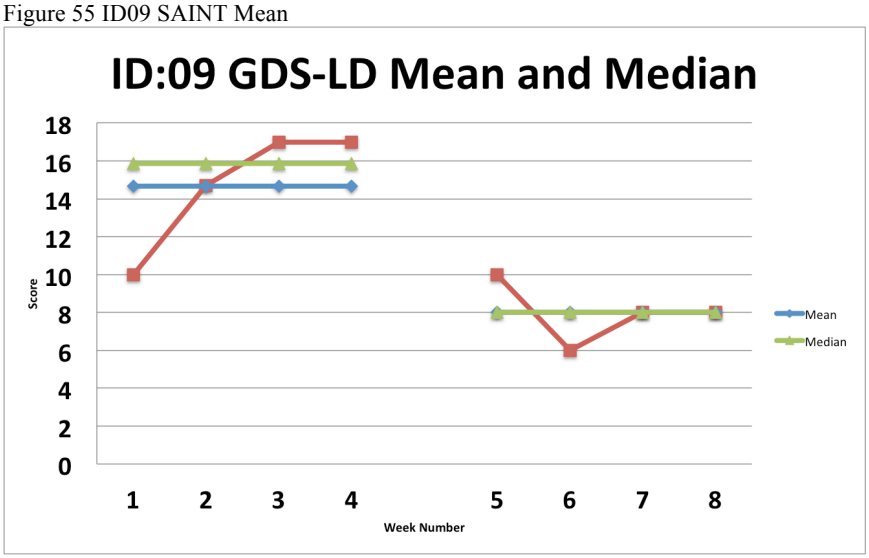

Figure 56 ID09 GDS-LD mean

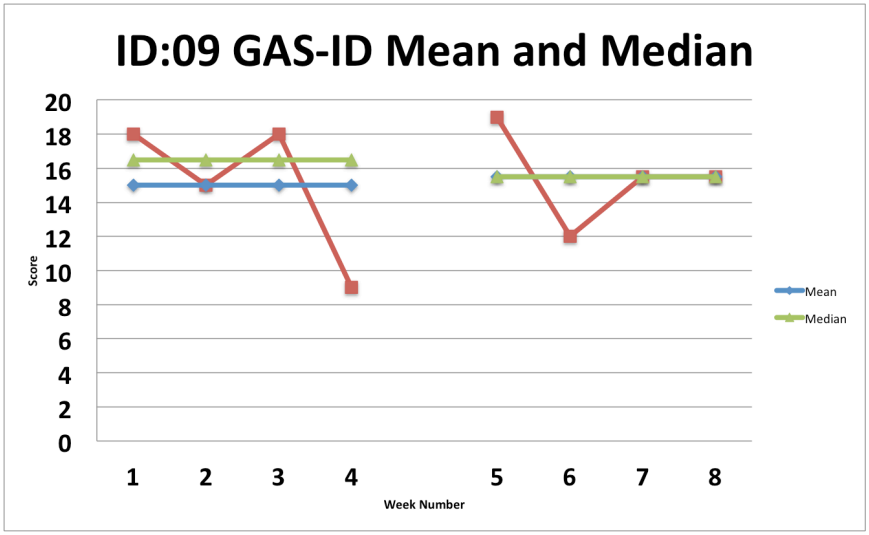

Figure 57 ID09 GAS-ID mean

5.13.3 Participant 10

IO is a 21-year-old male with a mild intellectual disability, who was subject to formal supervision in the community following discharge after an acute psychotic episode. During the sessions IQ participated and used the SAINT independently between sessions. Scores however showed wide variation during both the baseline and experimental phases (see Figure 58-59), this may have been due to a spell when IQ had no medication for two weeks because of a prescription mix up. Following this IQ presented very differently in the remaining sessions often appearing paranoid to events around him. The tendency to feel everyone's problems were his responsibility was often perceived as interfering and intrusive and brought him into conflict with other residents. Mean scores at A1, B1, A2 and B2 are shown below. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded and shown in Table 24 below:

Table 24 ID10 weekly scores

	A	B	A	B
SAINT	4.3	7.3	5-3	**5**
GDS-LD	12	16.5	17.2	**12.8**
GAS-ID	9.7	11	12.5	**10.8**

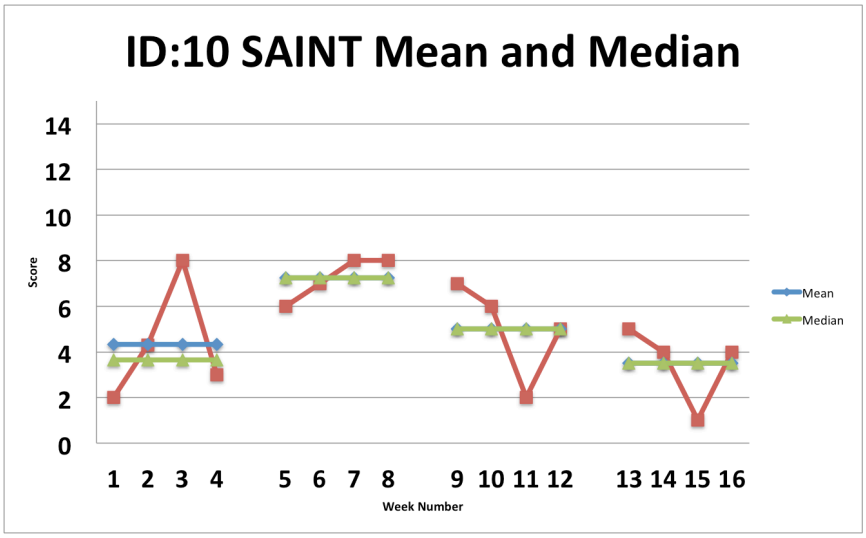

Figure 58 ID 10 SAINT Mean

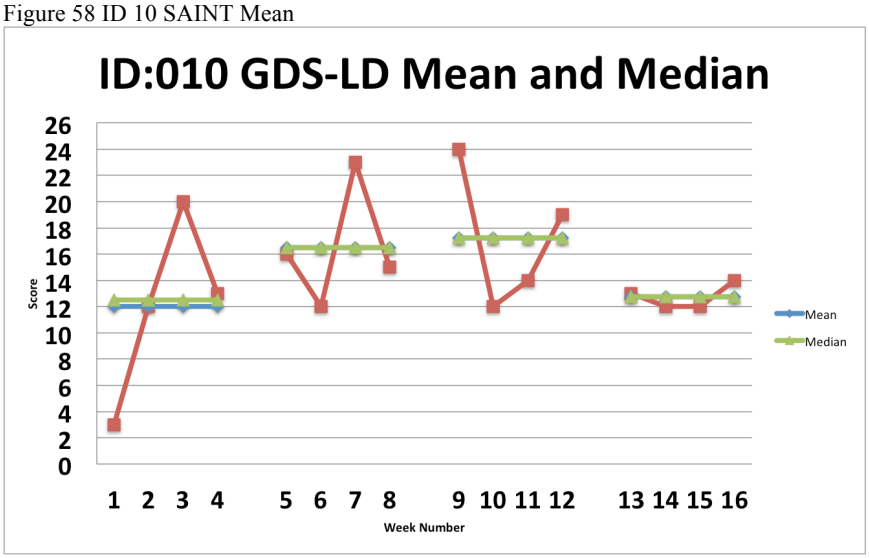

Figure 59 ID010 GDS-LD Mean

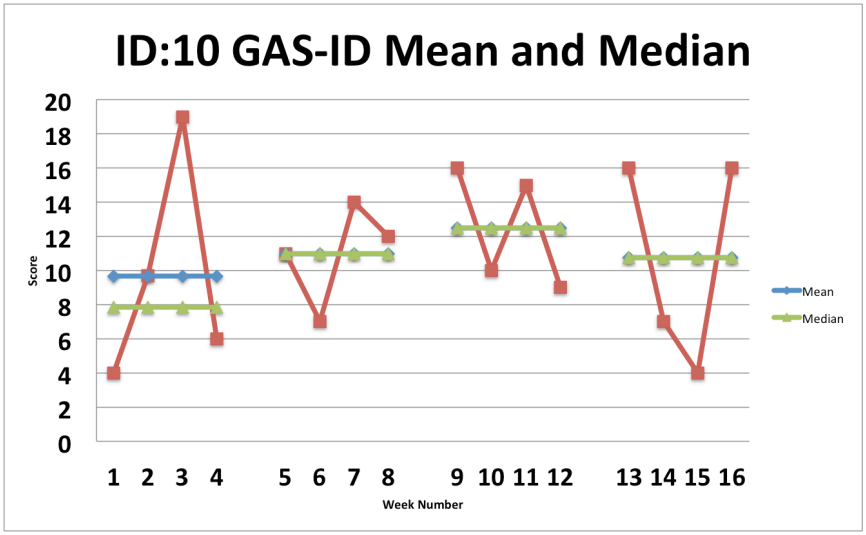

Figure 60 ID10 GAS-ID mean

5.13.4 Participant 11

LK is a 21-year-old male on a national inpatient assessment and treatment service with psychosis and a mild intellectual disability. Results from visual analysis failed to demonstrate any positive effect (see

Figure 61-62). These patterns coincided with an overall deterioration in mental state. The mean scores at A1, B1, A2 and B2 are shown below in Table 25. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded.

Table 25 ID11 weekly scores

	A	B	A	B
SAINT	4.3	7.3	5	**3.5**
GDS-LD	3	**2.8**	2	4.5
GAS-ID	2.3	2.8	0	1.8

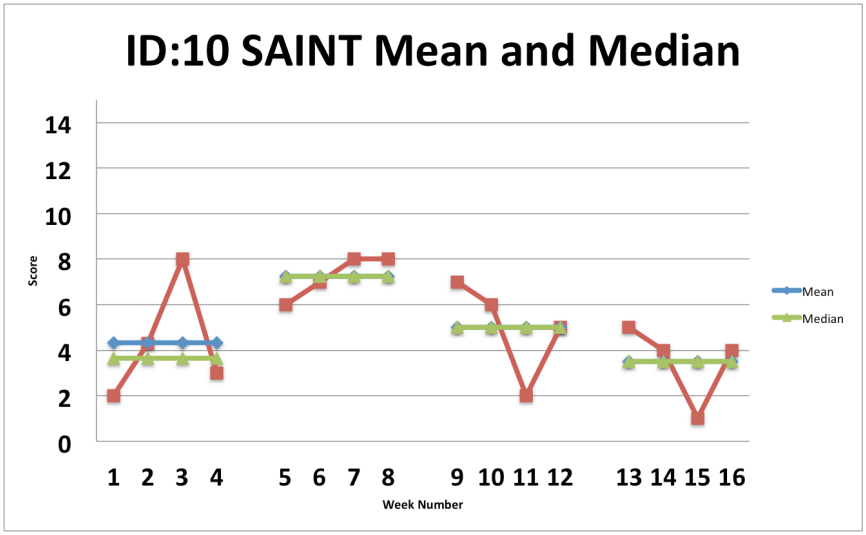

Figure 61 ID11 SAINT mean

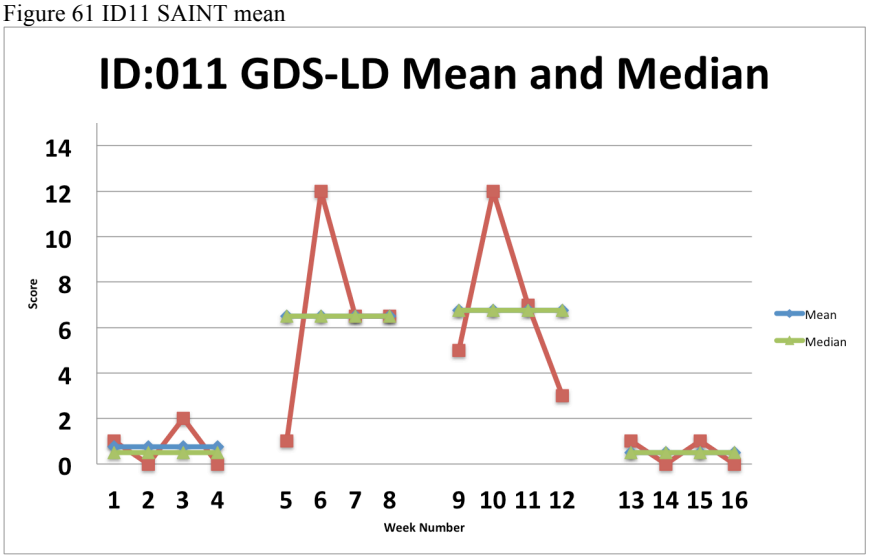

Figure 62 ID11 GDS-LD mean

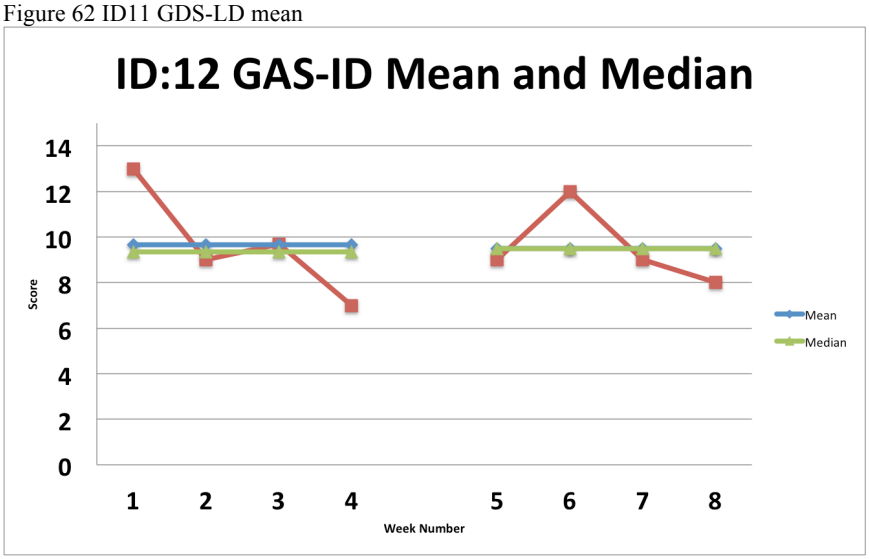

Figure 63 ID11 GAS-ID mean

5.13.5 Participant 12

BB was a 23-year-old female diagnosed with intellectual disability and a personality disorder and accessing community services after an escalation of assaultative and threatening behaviour in her home thought to be due to poor anger management skills. She has a mild intellectual disability and completed three phases of the SAINT. Although satisfaction with the approach was present this was not reinforced by the visual analysis, see Figure 64-65. Mean scores at A1, B1 and A2 are shown below in b. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded see Table 28.

Table 26 ID12 weekly scores

	A	B	A
SAINT	7.7	**6.8**	6
GDS-LD	12.7	13.8	11.5
GAS-ID	9.7	**9.5**	8.5

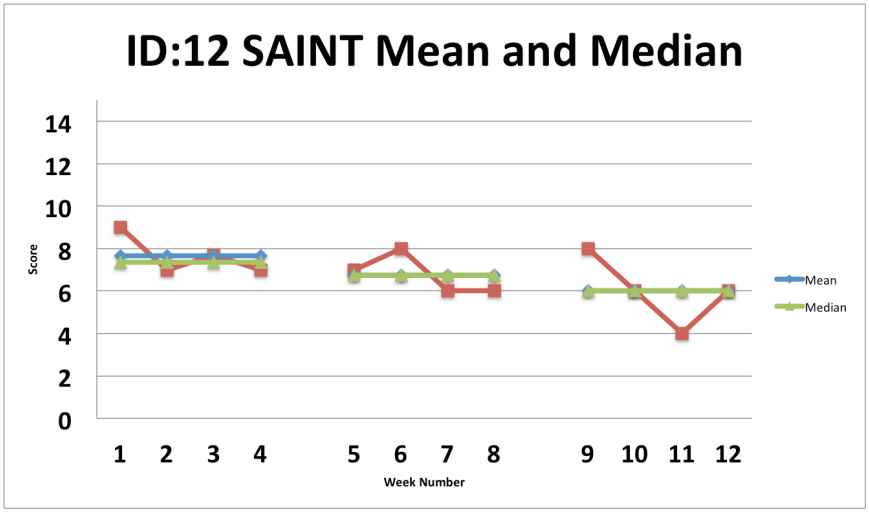

Figure 64 ID12 SAINT mean

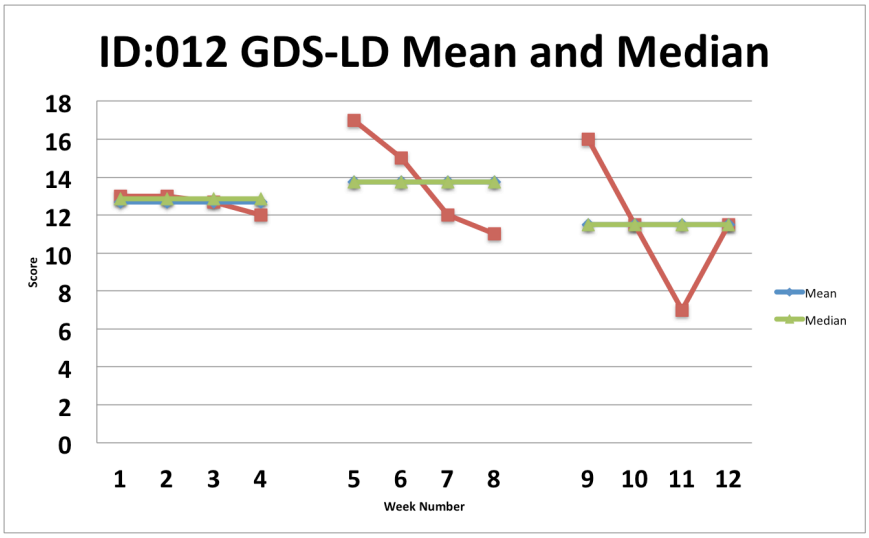

Figure 65 ID12 GDS-LD mean

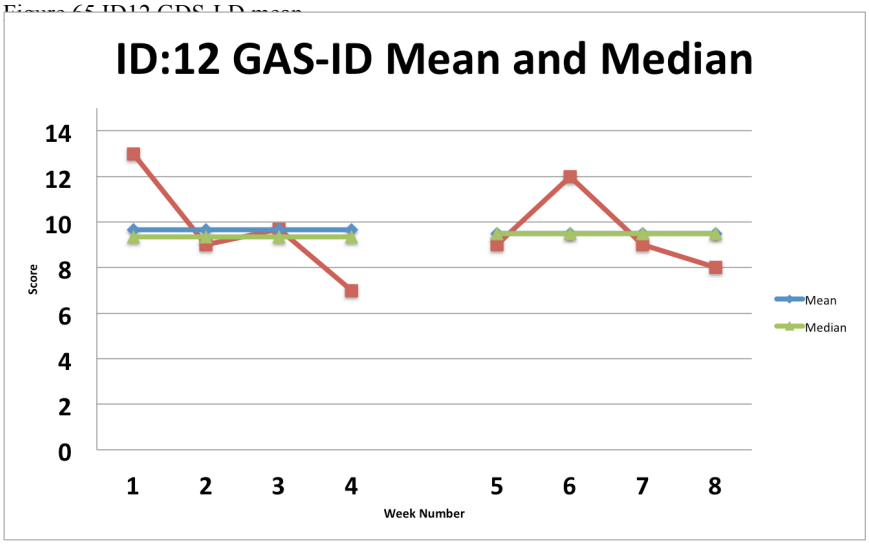

Figure 66 ID12 GAS-ID mean[i]

5.13.6 Participant 15

GG is a 26-year-old male with a mild intellectual disability within a national assessment and treatment service. GG has positive results across the SAINT, GDS-LD and GAS-ID evidenced by decrease to mean scores in the intervention phase see Figure 67-68. Unfortunately he was discharged before completion of the 3rd and 4th phases.

Mean scores at (A1 and B1) are shown below in Table 27. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 27 ID15 weekly scores

	A	B
SAINT	3.8	**1**
GDS-LD	12	**9**
GAS-ID	7.8	**5.5**

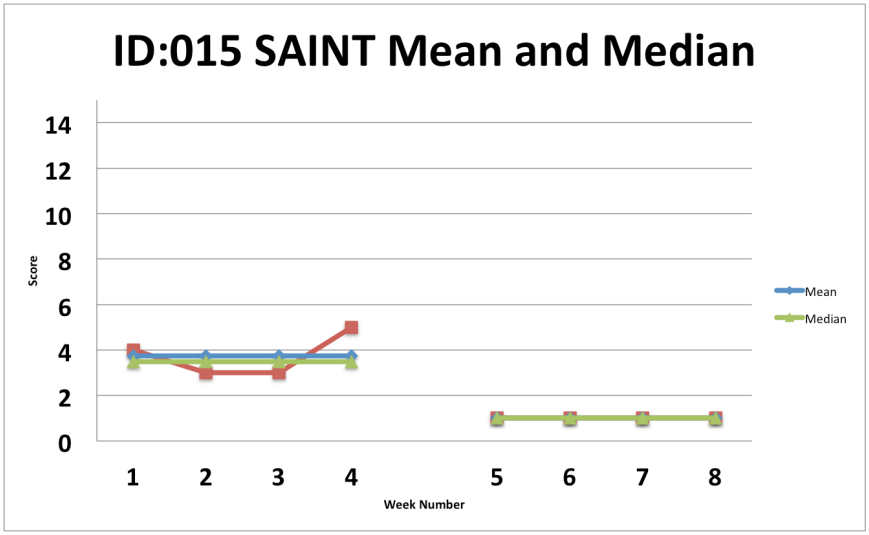

Figure 67 ID15 SAINT mean

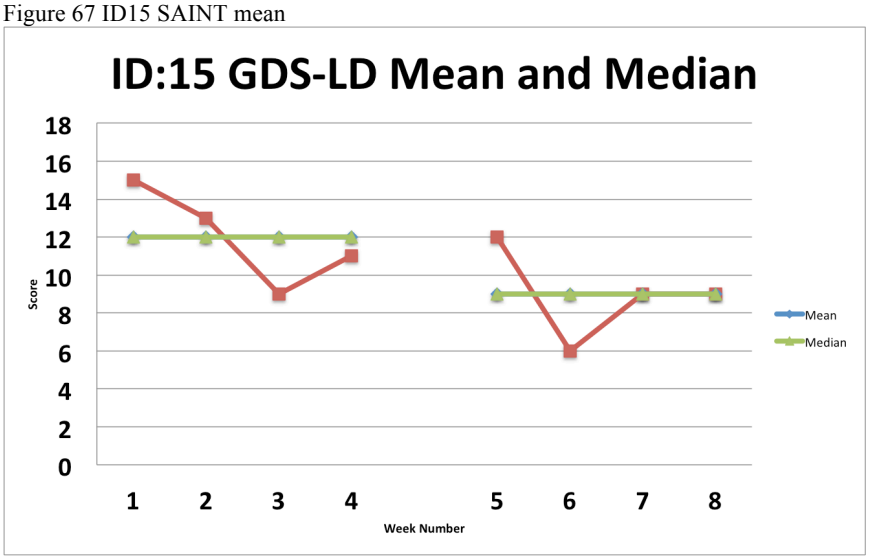

Figure 68 ID14 GDS-LD mean

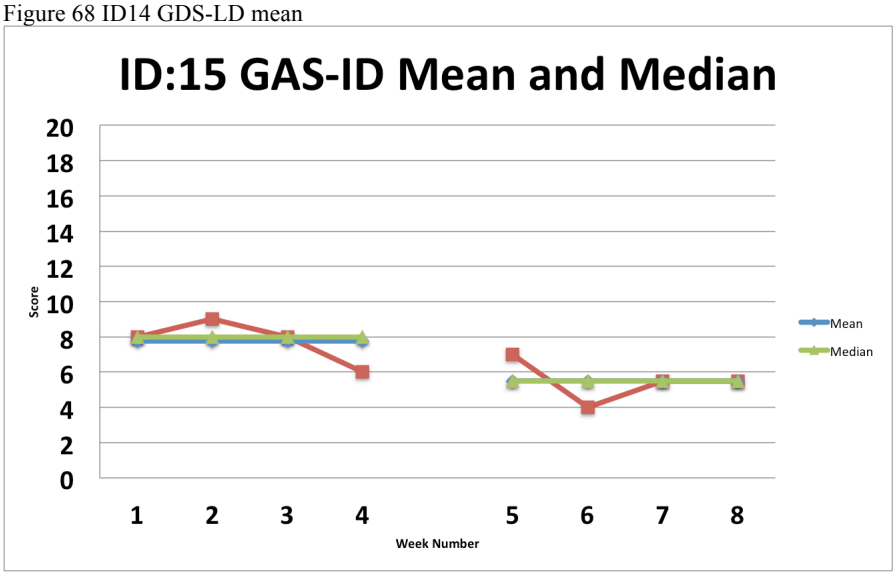

Figure 69 ID15 GAS-ID mean

5.14 Part 2

In part 2 there were 3 participants. This included two cases (both with histories of depression and anxiety) from part 1 to see if positive results could be replicated.

5.14.1 Results Grading

The results are presented and graded as follows:

1. Participants with a decrease in mean scores in both intervention phases across all measures
2. Participants with decreased mean scores in 1-2 measures in both intervention phases
3. Any other result

5.15 Participants with a decrease in mean scores in both intervention phases across all measures

5.15.1 Participant EB03

MQ was participant 8 from part 1 of this study. MQ participated and engaged with the SAINT during sessions and reported to using it between sessions both alone and with support. The results from part 1 were improved upon and mean scores decreased in both intervention periods using an extended baseline period (A) and longer phases (BAB) across all of the measures. See tables for EB03 across the SAINT, GDS-LD and GAS-ID. See Figure 70-71. Mean scores at A1, B1, A2 and B2 are given below in Table 28. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 28 IDE003 weekly scores

	A	B	A	B
SAINT	2	**0.2**	1.2	**0**
GDS-LD	2	**1.6**	2.6	**1.4**
GAS-ID	2.6	**1.4**	1.8	**1.2**

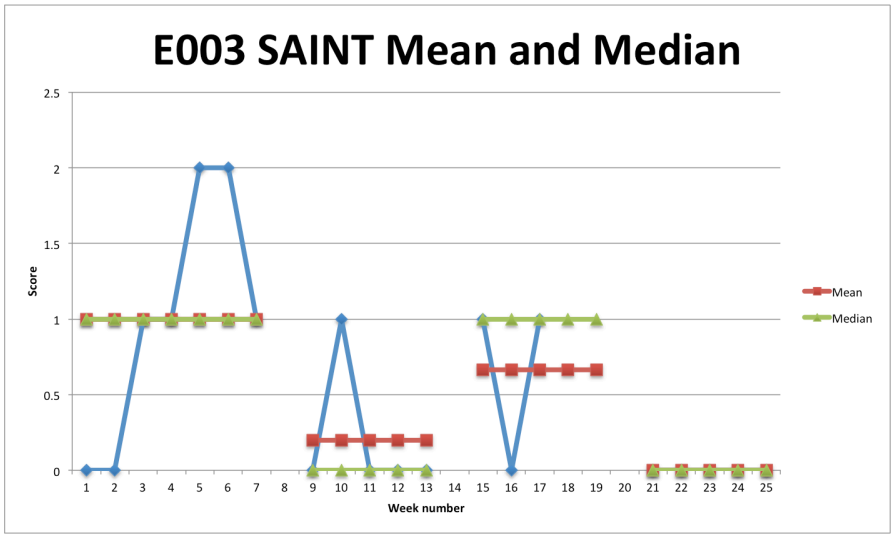

Figure 70 SAINT mean EB03

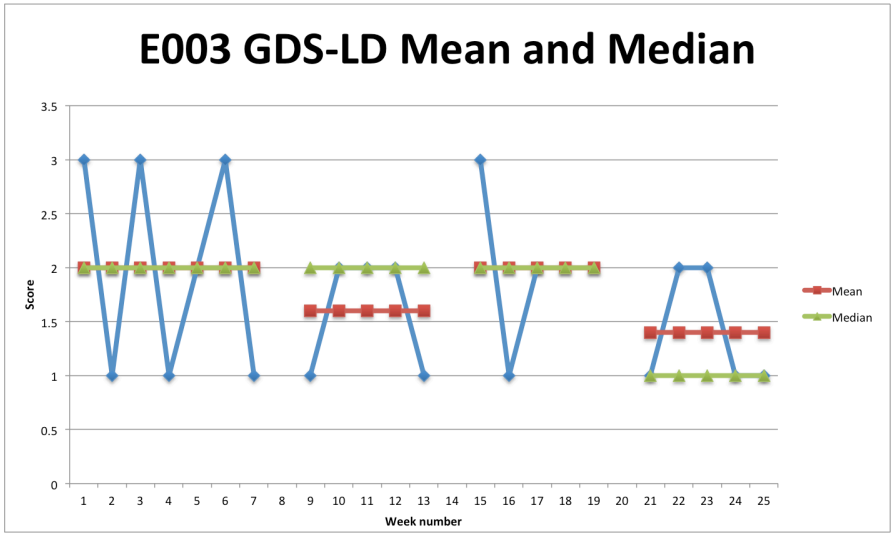

Figure 71 GDS-LD mean EB03

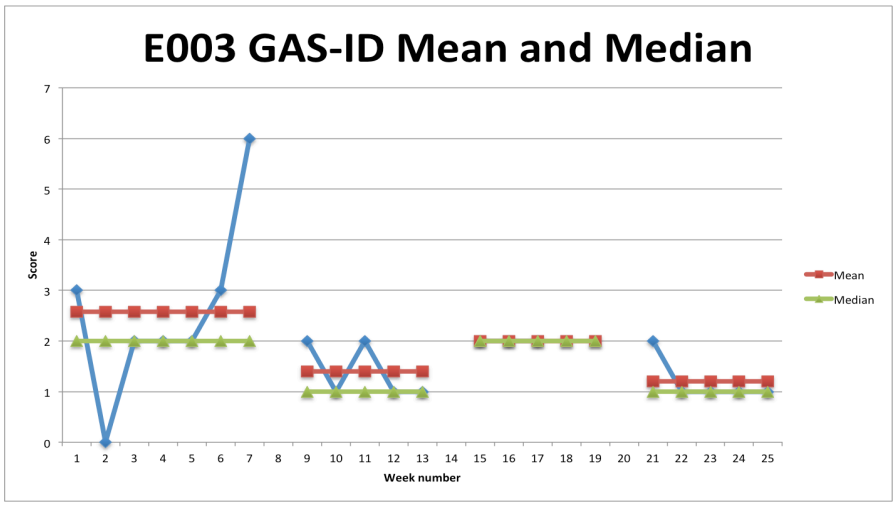

Figure 72 GAS-ID mean EB03

5.16 Participants with decreased mean scores in 1-2 measures in both intervention phases

5.16.1 Participant EB01

EE is a 58-year-old male with a mild intellectual disability diagnosed with personality disorder with a history of depression. EE is a widower and currently receives specialist mental health services designed for people with intellectual disability and has regular Community Psychiatric Nurse (CPN) visits. EE lives in a house with one other man and is supported part of the day by a visiting support worker. EE showed improvement in both intervention phases for the SAINT and GAS-ID and in one phase for the GDS-LD, see Figure 73-74.

EE used the SAINT during weekly visits in the intervention phase and with staff support between sessions. The issue that was mentioned consistently was a desire for companionship and friendship. EE chose not to be available for the last two sessions. This appears to have been a personal choice according to his CPN.

Mean scores at A1, B1, A2 and B2 are shown below in Table 29. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 29 IDE001 weekly scores

	A	B	A	B
SAINT	2.6	**2.3**	3.6	**2.7**
GDS-LD	3.9	4	6.2	**3.7**
GAS-ID	4.9	**4.3**	5.2	**2**

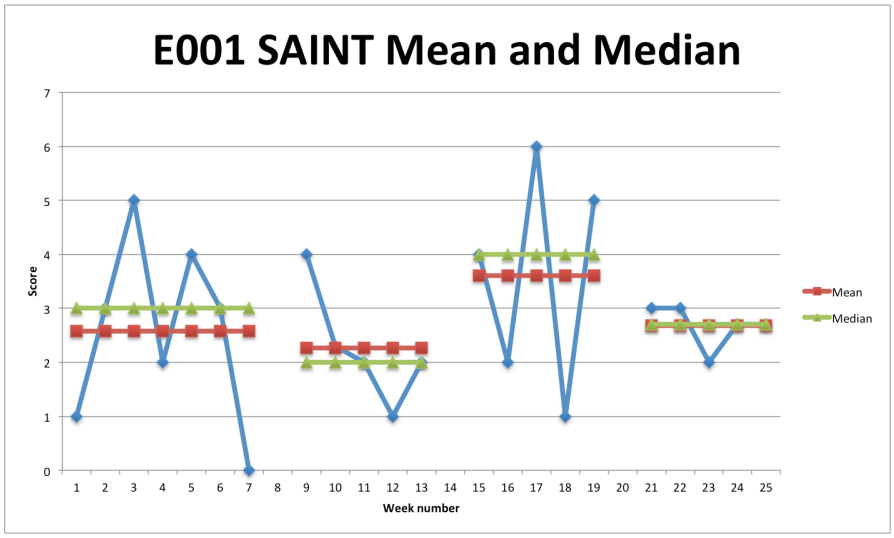

Figure 73 SAINT Mean EB01

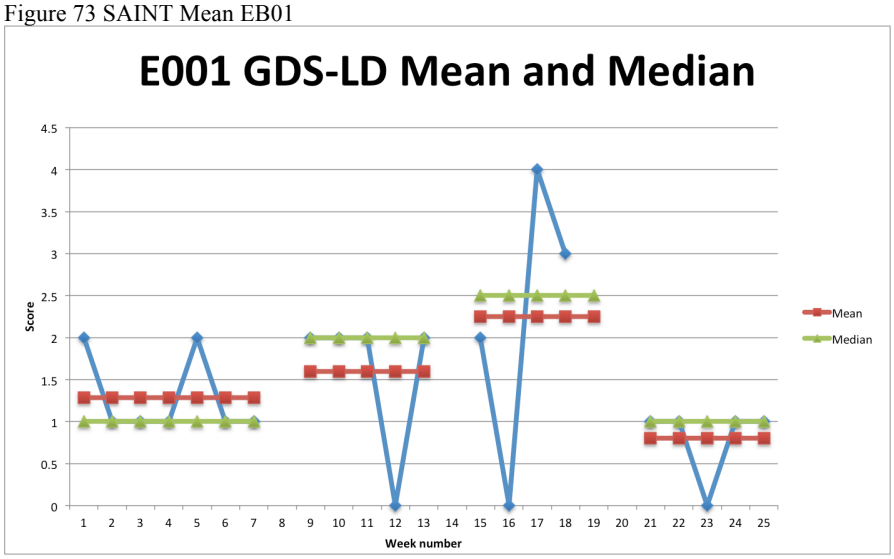

Figure 74 GDS-LD Mean EB02

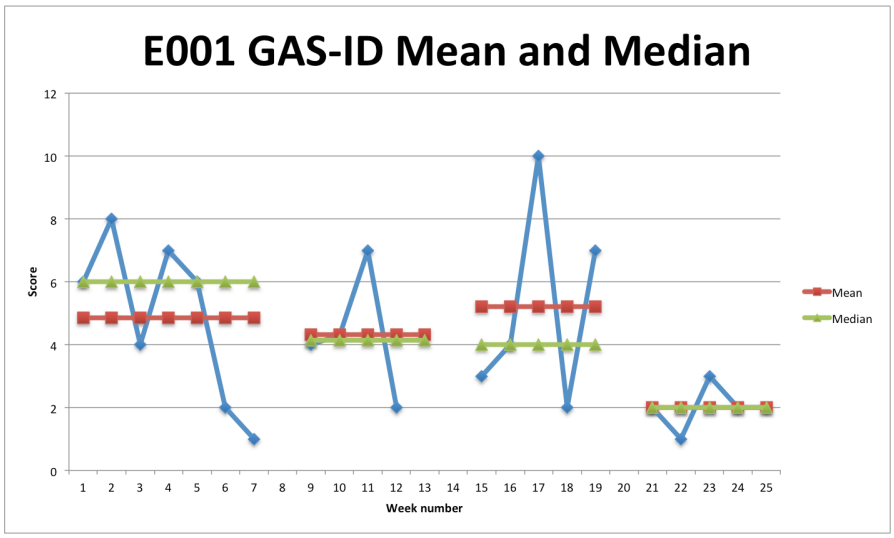

Figure 75 GAS-ID mean EB03

5.16.2 Participant EB02

QD was participant 7 from phase 1 who repeated the exercise over the longer time period to see if earlier results could be replicated i.e., decrease mean scores across the intervention phases. Since phase 1 QC had enjoyed a greater level of independence having moved from 24 hour supported living and was now being supported by daily visits from outreach workers. During sessions he engaged well and continued to use the SAINT in spite of not reading in between visits. QD approached staff when he required assistance although not all staff were willing to engage with him.

The results from part 1 were repeated with mean scores decreasing in both intervention periods over an extended baseline period (A) and longer phases (BAB) in the GDS-LD and GAS-ID. The SAINT showed a decrease in mean scores in the final intervention phase; see

Figure 76-77. Although there was a high fluctuation in scores within phases using the SAINT it was able to demonstrate that QD was able to identify feelings and use

coping strategies accordingly. Mean scores at A1, B1, A2 and B2 are shown below in

Table 30. Any decrease in scores for self reported symptoms during the intervention phases (B) are bolded:

Table 30 IDE002 weekly scores

	A	B	A	B
SAINT	1.3	1.6	2.6	**0.8**
GDS-LD	4	**2.8**	6.6	**2.8**
GAS-ID	1.2	**0.6**	3.6	**0.8**

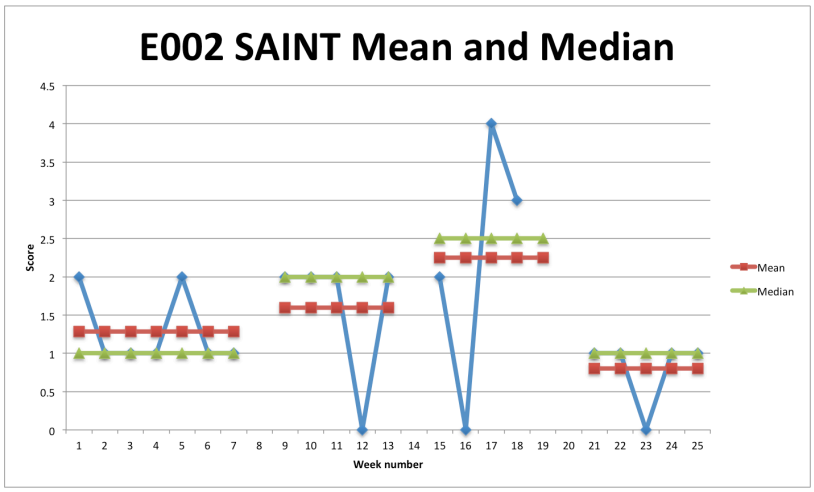

Figure 76 ID E02 SAINT mean

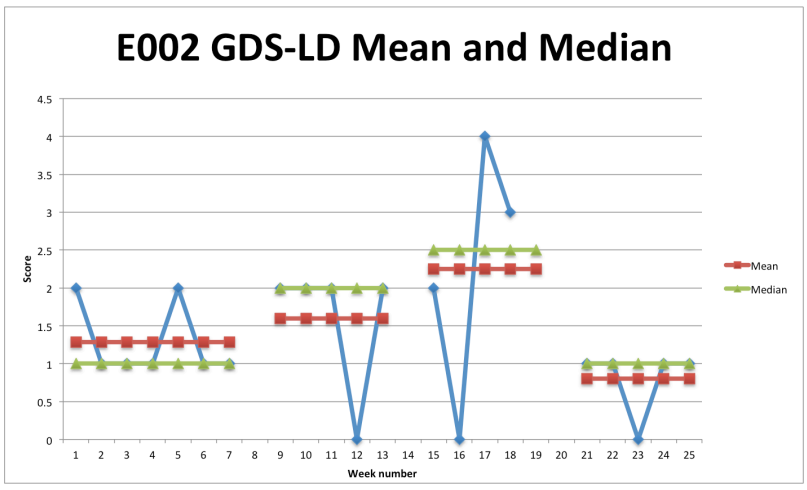

Figure 77 EB02 GDS-LD mean score

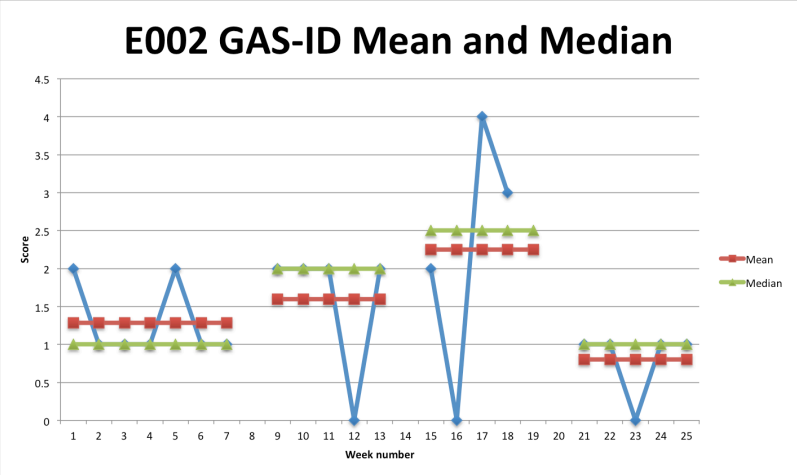

Figure 78 EB02 GAS-ID mean score

5.17 **Overview parts 1 and 2**

In part 1 of the study of the 12 participants who completed the intervention, 9 (75%) demonstrated a positive effect in both intervention phases using the GDS-LD in terms of decreased symptom scores. This compared with 6 (50%) participants using the SAINT and 3 (25%) using the GAS-ID. None of the 3 participants who failed to show improvement in the GDS-LD had a history of depression, although 1 scored above the diagnostic threshold on the GDS-LD during the study[4]. Two of the 9 participants that showed improvement met the cut off score for depression. In part 2, improvements to scores in both intervention phases were seen for all 3 participants using the GAS-ID. This compared to improvement in 2 out of 3 cases for the GDS-LD and SAINT. The GAS-ID (which had failed to show improvement in the majority of cases in part 1), performed better over the extended baseline and

[4] For the GDS-LD a cut off score of 15 is required to achieve 100% specificity (those without depression being correctly excluded) and 90% sensitivity (identifying those with depression) To improve sensitivity and avoid false positives a cut off score of 13, which the authors recommend for screening, increases sensitivity to 96%, with specificity lowered to 90%.

extended phases in part 2. This pilot in examining proof of concept has shown that people with intellectual disability have been able to use GSH.

5.18 Completion of sessions

The intervention was tolerated well with overall attendance for the intervention over 8 sessions (part 1) and 10 sessions (part 2), over 86% see Table 31.

Table 31 Sessions completed during the intervention phases

Sessions Attended	Sessions Missed	% Attended	
83	13	86.40%	Part 1 *n*=12
27	3	90%	Part 2 *n*=3

5.19 Discussion study III

The participants within the study have shown that people with intellectual disability can use GSH techniques and report benefit from them. The SAINT has also shown its utility and potential for future use in clinical practice by reduction of mean scores of symptoms during intervention phases for the majority of participants. Furthermore, these results were replicated under the more demanding conditions of the new SCED quality standards over a longer time period.

In part 1 of the study decreased mean scores during both intervention periods was seen for 3 participants across all measures using the SAINT manual. This was replicated for one person in part 2. Decreased mean scores were seen across two measures for another 3 people in part 1, one of whom replicated the improvement in

two measures. The control participant in part 2 also achieved improvement in two measures. User experience and satisfaction is addressed in chapter 7.

Recruitment to part 1 of the study challenged previous assumptions that few patients refuse to participate in research (Gray, Wykes, Parr*, et al*, 2001). A number of challenges to recruitment were encountered with accessibility to potential participants difficult. Ethically there is the need to ensure mechanisms are in place to both protect the person from unwanted approaches but at the same time allow those who want to participate to do so. Another issue is to ensure the person understands the research and has capacity to participate. This is a particular challenge in people with intellectual disability where cognitive impairment can affect a number of areas including: attention, memory executive functioning and communication. Low recruitment rates in this group can be for a number of reasons including non-response to requests and support workers saying no on the persons behalf and stopping approaches. There needs to be a mechanism that gives the person choice and/or informing them of the approach but that also affords them protection from exploitation. In Study 2, (reliability and validity) recruitment attempts by mail to house managers yielded no recruits. Follow up by phone to the houses offered only very limited success. Recruitment problems are not restricted to smaller studies but have also affected international multi-centre studies involving people with intellectual disability. The NACHBID study (Tyrer, Oliver-Africano, Romeo*, et al*, 2009; Tyrer, Oliver-Africano, Ahmed*, et al*, 2008) had an original recruitment target of 120 patients. The recruitment rate of 1.9 per month, created a higher than assumed drop out rate of 20%. Low recruitment rates in three of the UK centres meant that the use of research assistants at these centres could not be

justified. The role of intermediaries in recruitment is well recognised (Nicholson, Colyer & Cooper, 2012). In this present study a number of groups were identified with access to existing caseloads were approached to assist recruitment. The aim was for clinicians to offer an initial explanation of the study to potential participants, if they were interested to see if an approach would be welcome. Unfortunately this was not always successful. A number of those put forward were in acute or disturbed states rather than those meeting the eligibility criteria. In terms of attrition participants from inpatient services were the most likely to drop out. This was for a number of reasons including relapse, illness, discharge and sporadic engagement. Follow up was not possible for a number of people who had been admitted from other parts of the country. Also people living together or within the same service had to start the process at the same time to prevent contamination. The experience from part 1 informed recruitment in part 2.

The quality indicators used in part 1 included describing the participants, the process, the setting and critical features. Having a quality framework offers the precision and detail needed to replicate the study if required (Horner, Carr, Halle*, et al*, 2005). In part 2 a new set of quality standards for SCEDs by (Kratochwill, Hitchcock, Horner*, et al*, 2010), were adopted. The new standards required a greater level of evidence prior to making any meaningful interpretation of the evidence. These included having at least 5 data points in each phase [4 then 3 etc.] and the need to complete the intervention with at least 3-5 participants to make any valid conclusions. During the interpretation of evidence a number of issues were considered e.g., possible carry-over effects i.e., the intervention continues to work in the next phase or it has not had time to effect any change. Other considerations for

SCEDs such as order effects was not an issue as only one intervention was used so was not a threat in terms of biasing the study. Another potential issue that can occur in studies and considered during the application for ethical approval is the withdrawal of treatment or introducing treatment that cannot be reversed.

In SCED observations are recorded over time and evaluated using visual analysis. The evaluation works on the assumption that if change cannot be clearly seen then it is probably not there. Good practice requires two people to confirm findings. Single subject research is often dismissed due to limited insights into its purpose. This type of design is experimental in nature and aims to establish the effectiveness of an intervention over a period of time during baseline and after an intervention whilst being able to manipulate the experimental design according to the circumstances and add a series of intervention if indicated (Borckardt & Nash, 2002). Unlike a RCT, the SCED lends itself to modification by adjusting and changing of the independent variable to examine its effect on the dependant variable. The aim is to build up the intervention profile to build the evidence base. SCED aims to establish the effectiveness of an intervention over a period of time on a group or individual.

Although there are reports of SCED analysis using non-parametric approaches this is only indicated in large datasets. The study used a systematic approach to the interpretation of visual analysis using objective criteria; by assessing the following; level, trend, variability, overlap, immediacy and consistency. There are alternative methods e.g., (Kazdin, 2003), listed four criteria to assist analysis (1) change in mean rate of the behaviour from A-B, (2) change in slope from A-B (3) shift in level from A-B (4) a small latency to change from one phase to the next similar to

immediacy. This study used the more comprehensive 6-item analysis, but found it had limited value in this study in terms of interpreting results with the "level" or mean the most consistent indicator. It may be that alternative ways of interpreting these types of dataset is required.

In terms of group differences the results highlighted that people with mild intellectual disability had consistently higher symptom scores of depression as opposed to those with moderate intellectual disability. The reduced cognitive functioning of the moderate group and reduced ability to articulate would support such a finding. Also females scored higher than males which is consistent with higher rates of depression found in women within the general and intellectual populations.

The study also showed that the participants with ASD were able to benefit from the SAINT and demonstrated there is potential for the use of GSH approaches for people with intellectual disability and ASD. A previous attempt to conduct a pilot study on GSH in this group had failed to report results (Davidson, 2010). This current study had issues in recruitment (study 2) and in terms of drop out rates (Study 3). To address the issue of and to prevent attrition a mobile number was given to all participants or their carers and/or support workers in study 3. This was to cancel or rearrange appointments both to offer choice and to prevent the waste of resources. In reality only a handful of people used the mobile number and those that did, did so appropriately, although one participant rang to wish the PI a Happy New Year.

During the study a number of participants were subject to serious and untoward incidents during the study including sexual assault, emergency care following self-

injury, admission to local mental health services, being befriended to extort money and reports of bullying and harassment. To eliminate the effect of these types of experiences on results, data collection over a longer period would be required.

In terms of the mental health status of the group, two participants scored above the diagnostic threshold for depression, although only one had a clinical diagnosis. In terms of the measures used the five people with a history of clinical depression scored higher in each of the rating scales. The majority of this group were not clinically depressed during the study but all were subject to serious threats to their mental wellbeing, helping to prove the concept that GSH can be used in people with intellectual disability.

In terms of GSH as an intervention, there needs to be an understanding of when and for whom it is indicated. The inclusion of a wide range of participants in terms of diagnosis was purposeful to see which groups were most likely to benefit from the intervention, given the heterogeneity of those with intellectual disability. GSH once established in this group should help fill a vacuum. It has been suggested that the failure of coping strategies (central to GSH) is the reason people first seek help rather than severity of symptoms (Khan, Bower & Rogers, 2007). The SAINT was designed to help those seeking help and to build upon their existing knowledge to promote self-reliance. The role of the facilitator is to help the person both learn and build upon their existing strategies on a journey to develop expertise of their condition and to find out what works best for them. Part of any treatment should be to acknowledge and include those who can help support the person. The development of an effective therapeutic alliance can impact on whether users

subsequently use self-help (Glasman, Finlay & Brock, 2004). To assist those supporting people using the SAINT, both teaching and a training manual were developed. Currently there is no consensus on what constitutes effective training for care staff. van Oorsouw, Embregts, Bosman*, et al* (2009) considered 55 studies in a meta-analysis to examine three training methods for staff working with people with intellectual disability. In-service training consisted of classroom/workshop training, coaching-on-the-job, or a combination of in-service training and coaching-on-the-job. They concluded that the combination of in-service with coaching-on-the-job bought about the best results. However training staff in interventions to bring about behavioural change had poorer outcomes that non-skills based training. This current study developed a system of co-training for both recipients of the intervention and for those supporting them. It is not clear whether this had a more positive effect on the staff and a much larger dedicated study would be required to draw any firm conclusions, given the factors influencing staff training, such as a person's motivation, learning capacity, support to learn and the environment or the culture of the organisation they may work for (van Oorsouw, Embregts, Bosman, *et al*, 2009).

In terms of resources used, compared to other GSH studies this current study held weekly sessions that lasted between 15-30 minutes. This compares to an average duration of just over 40 minutes in a study reported earlier this year (Williams, Wilson, Morrison*, et al,* 2013). The increased frequency and shorter duration is suited to the adaptations required to ensure understanding of the materials and treatment given the cognitive impairments and deficits of the participants.

In terms of adherence of the 15 people who are reported using the SAINT in part 1 and 2, 87% (110/126) completed all of all sessions. In part 1 (*n*=12), 86.4% (83/96) were completed, and in part 2 (*n*=3), 90% (27/30) sessions were completed. This current study reported good participant attendance compared to Williams and colleagues, 2013, where only 45% attended all three sessions (reported in chapter 1). This may be due to a number of factors, including flexibility to choose the location of the intervention and the expectation to attend sessions.

CHAPTER 6 FEEDBACK AND FUTURE DEVELOPMENT

6.1 Introduction

This chapter reports the results of user feedback that was collected to inform the future development of the SAINT along with user satisfaction of the experience.

6.2 Methods

All participants who agreed to participate in part 3 of the study were asked to undertake a semi-structured interview to comment on their experiences using the SAINT. In total 16 participants (M=9, F=7) were eligible to take part. Of these six (M=3, F=3) declined and ten (M=6, F=4) were interviewed.

The interview sought to address a number of issues including, how people had used the SAINT e.g., what levels of support had they received, the ease of use, likes and dislikes, and what they might change and did the way they used it reflect the original instructions. All interviews were taped and transcribed for accuracy. As well as the interviews, field notes were made of all comments received from participants and those supporting people using the SAINT. Semi structured interviews are exploratory in nature and designed to provide a framework to allow coverage of main areas under consideration, whilst allowing for free dialogue and expression. It offers the advantage of starter probes which participants are encouraged to talk as widely as possible. This approach was chosen given the difficulty some might have articulating due to cognitive and social impairments.

6.2.1 Qualitative methodology

In the previous chapters the experimental nature of the study has been described. This part of the study used qualitative methodology to examine the thoughts and ideas of the participants in their own words. To do this a number of different qualitative approaches were considered which are listed below:

- **Case study research** - this involves studying a person(s) to examine a particular issue in depth, for examples experiences of people undergoing novel treatment.

- **Ethnographic research** is where the researcher examines and describes a given group and interpretation is based on defined areas common to the such as values, behaviors and beliefs.
- **Framework Analysis (FrA)** is a newer design that was developed to meet information needs and demonstrate outcomes in the context of applied policy research. It shares a number of features that are associated with other methods of qualitative analysis e.g., thematic analysis (Lacey & Duff, 2009). One of the benefits of FrA is that it allows concepts for analysis to be identified a priori (Dixon-Woods, 2011)
- **Grounded theory research** this method looks to conceptualise data. Originally it was used to originate social theory from research. In practice this is used now as a method to examine general ideas where the theories are grounded by the conclusions form the data.
- **Narrative research** focuses on the stories, of individuals to highlight their experiences. It then examines these chronologically to order the experiences

in intellectual disability research this method could be used to develop a life book

- **Phenomenological research** examines the meaning of common experiences on individuals. It seeks to generate descriptions to examine what underlies these experiences rather than seek to explain them through analysis.

- **Thematic Analysis** A method for analysing full and rich qualitative datasets to establish both implicit and explicit ideas. It lends itself to identifying co-occurrence of data, comparing frequency of themes to build a theoretical model

FA was selected from these as the chosen method of analysis as it offers a systematic approach that lends itself to scrutiny at all stages of the process. It has a number of similarities to thematic analysis and allows the examination of both pre determined themes and themes extracted from the data. Given the clear focus of the study and the difficulties of metacognition and reflection by people with intellectual disability FrA provides a suitable method of analysis, which has been described as "flexible, systematic, and rigorous, offering clarity, transparency, an audit trail, an option for theme-based and case-based analysis and for readily retrievable data" (Ward, D. J., Furber, C., Tierney, S.*, et al,* 2013, P. n/a online early). The basic principle is that the researcher having familiarised themselves with the data, extracts key themes that emerge from the data (Srivastava & Thomson, 2009). It is important this is allowed to happen and not to let a priori assumptions that have not been previously identified influence the collection and analysis of data.

6.2.2 Framework Analysis

There are five key stages of FrA (Ritchie and Spencer, 1994); which were used to analyse the interview data are listed below:

1. **Familiarisation** with the transcribed data.
2. **Identifying a thematic framework** this involves developing a coding system, and is a dynamic and ongoing process
3. **Indexing** involves developing a framework based on themes and the use of codes
4. **Charting** uses themes to develop charts that can be read across and are an interpretation of the dataset
5. **Mapping and Interpretation** is concerned with the future developments considering the findings

Among the strengths of FrA is that it can deliver information and outcomes over short timeframes with both a priori and emerging concepts.

6.3 Familiarisation

The first stage involves familiarisation with the raw data, i.e., interviews and field notes through transcriptions or recordings. It preliminary orders data in terms of how it relates to any a priori assumptions and potential themes prior to identifying the thematic framework.

6.4 Identifying a thematic framework

To identify the thematic framework, key issues were identified and built upon from the evidence to inform and develop a textual coding system. To do this a digital recorder was used to record interviews, which were transcribed for analysis. Many of

the transcripts were brief and offered an insight into the difficulty many of the participants have in expressing and articulating themselves to expand on answers to questions. In a number of interviews participants answered giving monosyllabic responses which may indicate a degree of suggestibility when answered in the affirmative. A series of iterations was used to bring sub-themes together however this was partly affected by some of the limited responses relating to the participants experiences.

Following familiarisation of the data a number of key themes were identified which were considered under the four headings see Figure 79. The semi-structured interviews were conducted and indexed following completion of the SAINT. Common themes within the text from the interviews were isolated in the thematic chart. Feedback on the SAINT was also received outside of the interviews from a number of sources including staff and user feedback during and after the study.

Key Issues Considered	
Personal Reflection	Where the SAINT has helped the person reflect on experiences
Barriers to use	Issues identified that affected using the SAINT to its full potential.
SAINT Utility	Benefits gained from using the SAINT.
Improvements to SAINT	Suggested improvements to the SAINT.

Figure 79 Key issues

6.5 Indexing

Indexing of interviews followed completion of the SAINT. Common themes within the text were isolated in the thematic chart. Feedback on the SAINT, was also received outside of the semi-structured interviews from a number sources including staff feedback and user feedback during and after the study.

6.6 Charting

A thematic chart was constructed to highlight themes from the interviews and any additional comments.

6.6.1 Thematic chart from semi structured interviews

The interview schedule provided the key stem questions see Figure 80 It was intended the questions were both uncomplicated and brief to aid understanding. During the interview participants were probed with additional questions to seek clarification or to allow the person to expand on their responses.

Semi-structured interview schedule V1

1. How have you been since I last saw you?
2. Have you used the SAINT
    a. If yes, how did you find using it?
    b. If no, why didn’ t you use it?
3. Were there things you particularly liked about using the SAINT?
    a. Could you tell me more?
4. Were there things you did not like about using the SAINT? …… (if No) What were they?
5. When do you use the SAINT?
6. Could you tell me how you used the SAINT in~?
7. Did you need help to use the SAINT?
8. Is there anything that could be done to make the SAINT better?
9. Is there anything you do not like in the SAINT that you would change?
10. Is there anything else you would like to tell me?

Figure 80 Semi structured interview schedule

The semi structured questionnaire (see Figure 78) was designed to gain feedback from participants who took part in the SAINT pilot. The aim of feedback was to learn about people’s experiences, the acceptability of the intervention and its use in clinical practice. This addressed a number of issues such as whether the manual had been used as intended, its ease of use, the level of support required and received and the possible need for any amendment to the materials or process.

The questionnaire used open ended questions with sentences structured to contain single points so that questioning could be structured to assist understanding. This was to assist understanding and not to confuse participants with difficulties with

recall or understanding. The questions were supplemented with probes to seek clarification or elaboration. The analysis looked at both negative and positive responses and evidence of suggestibility and/or acquiescence.

Thematic charts are constructed to isolate data relevant to the key themes identified across a transcribed interview dataset(s). This can be seen in Table 32; full transcripts of the interviews are available in appendix 6. One person recorded their experiences in an additional log, which they copied onto PowerPoint as a presentation, see appendix 7.

Table 32 Thematic chart from SS interviews

Themes	**Reference**	**Comments**
Personal Reflection	P5 Line 215	It helped me.
	P5 Line 236-37	Can you write to me and my Mum to give me the graph and say how I done.
	P7 Line 7-9	As well as negative stuff you have to think about the positive stuff because this year has been up and down for me, its been terrible to start with but now it is getting better slowly
	P7 Line 10	Moving, new job and new prospects are coming up for me.
	P7 Line 82-85	I try to remember the words of my mother to help me Positive thoughts, yes positive thoughts I try to remember the words of my wife to help me and other people telling me not to worry and the smiling faces cheer me up and all that depression sort of lifts.
	P7 Line 3-5	Found it very helpful a lot of people have written down feeling diaries sad and helpless sought of thing and has helped me with my moods as well. I write down how I an feeling it is a feeling book that helps me with my moods
	P7 Line 245-246	I read the book while doing my homework. I would read but not write in it the second time, which was as helpful I liked it
	P5 Line 225	Yes it was good.
	P5 225-226 P5 230-231	Good I liked the pictures and the flow. I filled it in my Mum helped me

Themes	Reference	Comments
	P5 Line 224	Yes it was good
	P7 Line 138	It was interesting
	P2 Line 102	I liked it
Barriers to use	P7 Line 57-58	Some staff can be sought of thing, not very helpful I said to R would you help me with my book. I did ask the night before so there was no excuse, they kept saying tomorrow in their own words, s Rainer is a lovely lady, sorry I do apologize and she said I wish you had asked me last night P***, well R I did actually ask a couple of staff here last night. She said because the evenings are better they say that the always the next day. She said she would write something in it when the mini cab come so my keyworker said we would do it outside but he didn't do it either, I thought this is charming he said don't worry P*** we will do it tonight but he did not do it
	P7 Line 63-70	Sometimes it is not easy to talk to staff all they will say to me some won't answer some will tell ne to sit down or what's the reason because there so bust looking after the other service users and they look at me because I am an independent man but that's rubbish because any one can get depressed so what I d is I use this book. So if no one is here to help me I will look at these pictures then
	P7 Line 77-82	Difficult.
	P7 Line 19-20	Staff have been busy doing things with other people Sometimes hard to understand.
	P3 Line 174	No they are too busy. Writing to small I am good at reading.
	P3 Line 174-175	I don't get the feelings, the questions are a bit hard to understand
SAINT Utility	P7 Line 6-7	It has given me the chance to think about my feelings am I depressed
	P12 Line 248	How to cope with stress,
	P12 Line 248	How to stop worrying
	P7 Line 13-15	Very good how it is laid out I can't read it but it looks understandable. I like the pictures; I am pleased it has pictures in. People with learning disabilities, help them to understand more rather than joined up writing. Did it on my own I found it very easy
	P12 Line 255-256	Yes it said things that help.
	P5 Line 201	It was easy.
	P5 Line 202	It helped me say how I was feeling?
	P5 Line 203	It was all right it was interesting.
	P7 Line 139-	I did it on my own. What I do each week, just good

Themes	Reference	Comments
	140 P7 Line 161	things. Would write about being worried. Yes I like meting others
	P7 Line 162	I like the book it is alright.
	P7 Line 163	It was easy.
	P7 Line 173 P7 Line 62-63	I like the coping strategies. I was feeling a bit depressed and left out so I got my book out
	P7 Line 73-75	It has helped me sometimes when I have a good cry I can look at it and say I was depressed or other reasons I can say I had a bad day.
	P7 Line 56-57	I used the book any time I get depressed, sometimes I use it during the day if I got staff I can talk to looks all right, I like the pictures
	P7 Line 30-31	I recognize by the pictures and it has been helpful.
	P4 Line 127	Sometimes hard to understand
	P7 Line 37	The pictures are also good for people learning to read and pick up words.
Improvements to SAINT	P5 Line 232-233	Photos rather than pictures.
	P5 Line 232-233	A place to put about gym and church (weekly planner for routine)
	P5 Line 214-215	Easy to tell someone if you're upset.
	P5 Line 234-23	Put more things in it what I am doing
	P3 Line 175-177	Print could be bigger. Pictures with different writing. Different books for different people big one and small one. I would like photos.
	P7 Line 31	Like brail for blind people
	P12 Line 257-258	More things to read especially good things about being well.

6.6.2 Comments made and/or received

The following additional comments and observations were made during or between sessions by participants and other researchers:

- The need to address a positive balance of both positive and negative emotions within the SAINT booklet - Although there were examples of how to use the materials when things were going well e.g., the diary, it was felt by some that this was not emphasised enough. This is an important issue that needs addressing if the manual is to encourage and promote a healthier lifestyle
- The examples used to reflect statements - Some examples within the SAINT were thought not to reflect what was being asked; in particular number 9 from the feelings chart. The statement for number 9 was "I feel emotional", and lists **"**My mood keeps going up and down", "I feel heartbroken", "I feel unwell" and "I am in pain". On first inspection there does not appear a logical link between the items, however it was used and identified with by participants and had been chosen by the SUE group.
- Ease of use - This point highlighted the issue that for some these approaches would be difficult or not even a viable option if there is a lack of required support either between sessions or to support the person to get to sessions.
- The wording e.g., number 10 is the wrong way around - The feeling "Looking after myself" and first example, "I am not taking good care of myself", were thought to be too similar to offer a distinction. However this observation did not affect the use of the SAINT in practice.
- Being asked about dying and bad things - Part of the assessment of outcomes involved asking questions relating to self harming or dying. For one person in particular this was distressing so the question was rephrased to accommodate this to," the thing we don't talk about has it been a problem this week, yes or no".

- The tendency for some staff supporting the person writing notes in the SAINT - This highlighted the culture of current staff within services where there was a maternal approach and/or a need to do things to people. By giving their opinion the person's independence was unintentionally compromised by the staff member as ownership and self help was taken away from them. A greater emphasis to be explain the SAINT as part of person centred planning

6.7 **Mapping and Interpretation**

The four key themes that were identified and developed following feedback from the interviews and synthesises were mapped, see Figure 75. The aim of mapping and interpretation is to add clarity to findings to consider ways forward for future development. The themes chosen reflected the learning from the charting exercise and will inform the next steps of the process to develop the SAINT. The themes considered were; *personal reflection*, which was encouraged for all participants during all aspects of the process, in particularly for those using the SAINT, current *barriers to use*, was also considered to gauge what if anything prevented the SAINT from being used to its full potential in practice, next the *SAINT Utility*, was examined to elicit the benefits using the SAINT bought to participants as an intervention, both those that might reasonably be expected such as decrease in symptoms of depression or those that might not be expected. The final theme was *improvements to the SAINT* this examined issues of presentation and what could be improved for those who might find it difficult, and how a wider proportion of people with intellectual disability might be reached or supported to use the intervention.

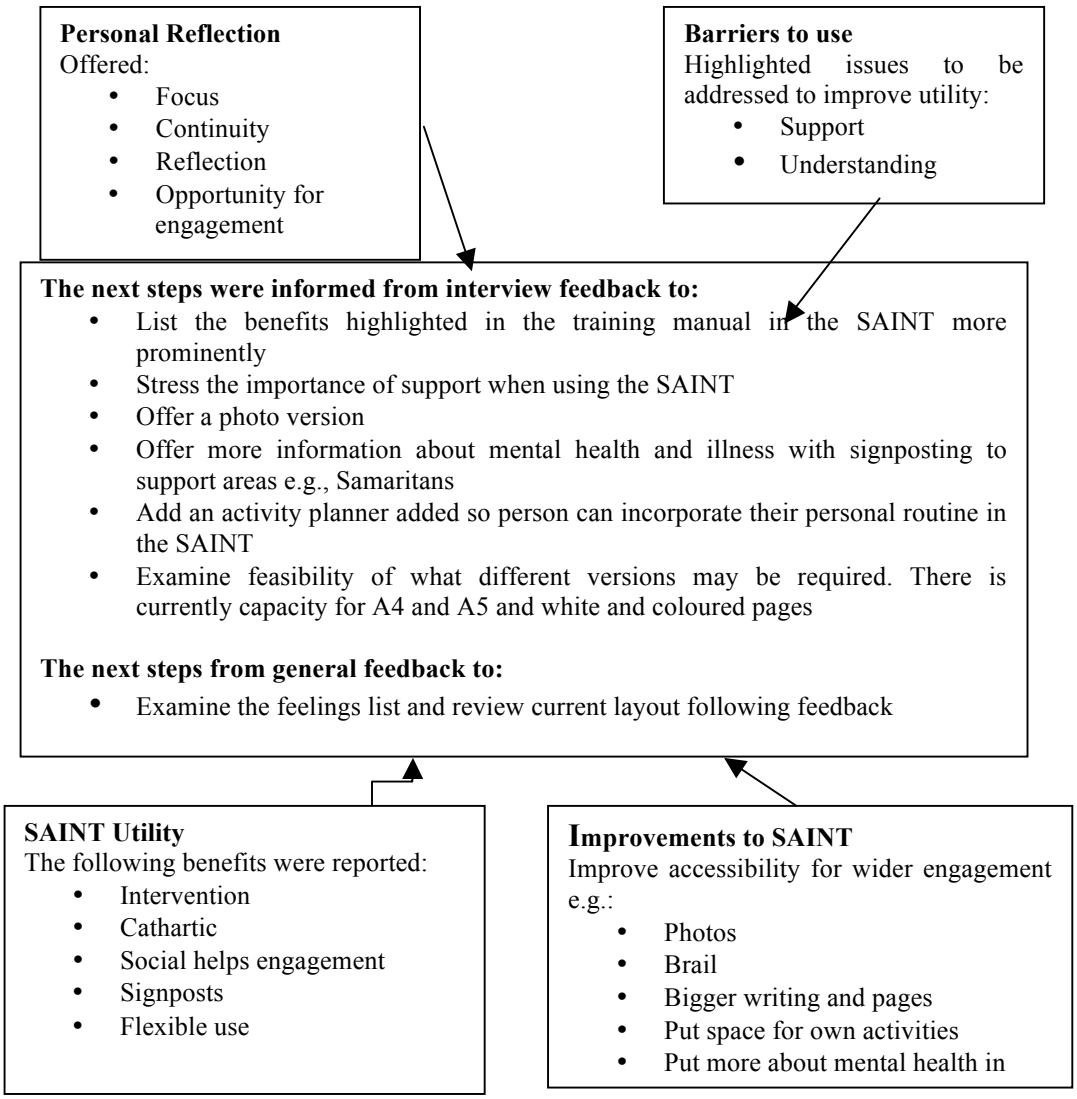

Figure 81 Mapping and interpretation

The contents of the chart from the previous page are expanded upon below:

- **Personal reflection** - the SAINT allowed participants continuity and the opportunity to focus on issues. For many it bought about increased engagement within existing relationship and allowed reflection.
- **Barriers to use** – a lack of support to use the SAINT between sessions was cited as why people may have not looked at the book between sessions. For a few the SAINT was found to be complicated, however through repetition many were able to use it with support. A number of participants found it

initially difficult to understand the process and order of the SAINT and what and where to write. The recognition of feelings was not always covered which was accepted as the person had normally gone through discussions with support staff about their day.

- **SAINT utility** – a number of benefits were reported about the SAINT as an intervention. Its flexibility afforded increased engagement socially. It also helped the recognition of emotions and confidence to seek help out of hours.
- **Improvements to SAINT** – the improvements suggested were mostly around presentation of the materials e.g., photos rather than pictures and centred on adding materials to the SAINT e.g., more information about mental health and mental illness, guidance on support, a personalised activity planner, to look at different versions to improve accessibility e.g., photos, different sizes of paper, fonts and paper colour.
- **Next steps –** the SAINT will be improved from comments including the addition of photos and more information about mental health.

6.8 Discussion

The complexity of effective GSH interventions lends itself to evaluation using qualitative methods, to help our understanding of how people use and experience interventions (Khan, Bower & Rogers, 2007). Personal feedback from people's experiences of using the SAINT, has offered a valuable insight into its utility in practice. All participants who offered feedback reported that they enjoyed or benefited from the experience of using the SAINT, with a number of people still using the SAINT following the conclusion of the study. Although many participants were unable to expand on, or did not wish to talk of their experience formally, those that could were able to give positive examples of how they used the SAINT, as well

as constructive criticism. The way the SAINT was used was individual to participants often to fit in with their routines. One person inspired by the experience chose to write about how they used the SAINT and how it could benefit others. The experience of people using the SAINT was positive, and improvement was often reported that was not always apparent in the visual analysis, in terms of increased engagement and time spent positively with staff. Some staff who had supported people to use the SAINT reported that they knew more about and better understood the individual they were supporting. The use of mixed methods and bringing together quantitative and qualitative techniques is increasingly looked on as a continuum (Niglas, 2006). The use of interviews and personal experience has added extra dimension to the study.

As in this study it is essential that service users opinions are canvassed throughout the process when developing a new intervention (Peterson, 2008). More radical researchers believe that research design is about choosing sides i.e., is the research for the person or the researcher. See (Nind, 2008) for a sociological perspective.

Qualitative methodology is concerned with finding order, patterns and structure to record and make sense of people's experiences. Traditionally this has meant that studies have been biased towards those people who can articulate their experience. However in intellectual disability, people are not always able to articulate due to cognitive and social impairments. This can cause problems with the quality of data in qualitative studies, as participants may be unable to expand on their answers due to a lack of poor expressive language. There are questions as to whether qualitative methods are a legitimate research tool in this group, but however it is accepted that there are barriers, these should not exclude people with intellectual disability. This would be akin to invalidating the experiences of the group. Many of the arguments

against are also as equally valid for other groups e.g., even those who are articulate may not be consistent with responses, which may be affected by situational factors such as being in a bad mood, in a rush etc. In spite of this with adaptations to how information is gathered there is no reason why people with intellectual disability should not take part on this type of research. In this study a number of considerations were made to improve engagement e.g., familiarisation and socialisation with the interviewer during weekly visits e.g., being able to have some one to support the person during the interview and not imposing a time limit on the interview. Although some interviews only had very short or monosyllabic answers, the negative responses were an important part of the validation process as they offer an indication that the person is not suggestible or acquiescing. This is an important part of the process and necessary to inform development. The negative responses included: parts of the SAINT were difficult to understand, not liking negative questions on harming themselves. All negative comments occurred in the context of a reported good overall experience. So although the responses in some cases were brief, they appeared to be a genuine expression of the experience, rather than as a result of acquiescence. In people with intellectual disability acquiescence can be a problem and can easily be overlooked or not considered by those with little awareness of this group. Because of this how we try to get the person to engage to record their experiences is crucial. This means that the design and administration of the interviews are all important so that data is reliable, particularly where there is no time to check the response or the person's motivation for the answers given e.g., to please the interviewer or to mask the fact that they have not understood what is being asked. On the whole participants viewed the experience of using the SAINT as positive and worthwhile.

CHAPTER 7 DISCUSSION AND CONCLUSIONS

7.1 Introduction

This final chapter critically discusses the methodology and results of the three studies within this thesis and examines the potential of the SAINT to improve the health and social well being of people with intellectual disability. The discussion makes reference to UK policy issues relating to intellectual disability and mental health as appropriate. An account of the strengths and limitations of this research and its implications for practice and future research is also provided.

It is accepted that people with intellectual disability ought to able to benefit from psychological interventions and that GSH embraces the principles of independence, choice, inclusion and rights which are central to UK intellectual disability policy (Department of Health, 2001). However in spite of encouraging results for the effectiveness of GSH in the general population, the comprehensive literature review found no evidence of GSH being used for people with intellectual disability apart from publications arising from the current study. GSH seeks to give the client more control over their mental wellbeing through the development of knowledge and skills aimed at recognition and management of their symptoms. As well as producing personal benefit GSH may prevent a deterioration in the sufferer's condition and so reduce the need for more costly and intrusive psychological and/or physical interventions.. Compared to other psychological treatments GSH offers greater versatility in terms of the resources required for its administration. One of the key advantages is that it can be delivered across healthcare settings by non therapists.

GSH is part of a greater range of mental health interventions which are now available within primary care settings. The placement of mental health screening, assessments and interventions in locations such as GP surgeries may have the added benefit of helping to break down the taboos around mental illness and help reduce the stigma associated with it. For GSH to be adopted and made available for people with intellectual disability, health care providers will be required to make reasonable adjustment to ensure that any treatment provided is made accessible and takes into account the communication needs of the person.

The three linked studies within this thesis were designed and modelled on the processes outlined in the MRC Framework for complex interventions (Medical Research Council, 2004; Medical Research Council, 2008). Adopting the MRC framework offered a systematic approach to measure progress and to facilitate a scientific basis for, and understanding of the intervention (Khan, Bower & Rogers, 2007).

7.2 **Study 1**

This first study developed the SAINT using the opinions of two expert groups (a group of clinical experts [CEs] and a group of service user experts with intellectual disability [SUE]. To achieve a consensus, Delphi methodology and focus groups were conducted over three rounds to develop and refine the contents of the SAINT self help manual. Following the first round of the Delphi (CEs) and focus group (SUEs), responses from both were pooled and shared. Participants were then given instructions to review their responses after considering this pooled information. For

the CEs, data was collected by email questionnaire, this would have been inappropriate for the SUE group given that many would have limited access to computers and/or the support required to engage in this way. This may be partly the reason why Delphi studies within intellectual disability research are still relatively uncommon. What studies there have been have adapted traditional methods. Although face to face interviews have been the preferred method within a number of intellectual disability studies using Delphi methodology (Hemmings, Underwood & Bouras, 2009, Bonell, Ali, Hall*, et al,* 2011), the present study used focus groups. This offered the advantage of peer support and ensured participation was possible within a familiar environment. The rationale for this was to help participants feel at ease, not be or feel singled out and to be able to consider the ideas and comments of their peers. The decision to recruit from established mental health groups ensured that participants had personal experience of mental health problems to draw upon. However the use of groups if not managed correctly or by someone with little awareness of the needs of people with intellectual disability could be disadvantageous. For example not being aware of some of the issues the facilitator may not know when it is appropriate to challenge, seek clarification or when to reframe their responses to individual members. Other issues that may need consideration are the groups' dynamics e.g., the group members may be interdependent on each other and/or provide responses that aim to please or acquiesce to the views of peers for fear of upsetting someone or standing out.

To ensure confidence in the quality of the data careful consideration was given to how the questions were framed and the discussion facilitated within the focus groups. For example, questions were framed both positively and negatively to assess consistency of response and to deal with the possibility that some people were simply agreeing to all questions in order to please the researcher or to hide a lack of comprehension. To assist understanding further, jargon in the responses of the CE group was interpreted into everyday language that was consistent with the SUEs responses about their personal feelings and experiences.

In total there were three focus groups for the SUEs and three rounds of email questionnaires for the CEs. Both the Delphi and the focus groups were arranged in parallel so that information could be shared between CEs and SUE in real time. All of the SUEs who enlisted in the focus groups completed the three rounds. Whereas of the 79 intended CE recipients, only 38 (45.5%) chose to participate in round 1 and only 15 (19%) completed all three rounds. The process of recruitment of CEs via the web and email was problematic. For example knowing whether the contact information for potential participants was up to date and the reliability of the chosen databases. A number of those identified as eligible and sent invitations to participate were unable to be contacted using the email addresses provided by the two national networks databases and their current whereabouts was unknown. Furthermore, although invitations to participate were sent individually, the absence of a face to face contact and the relative anonymity of the request is likely to have contributed to difficulties in recruitment and retention across the process. Although personal face to face interviews may have been a more successful method for recruiting the CEs the geographic spread of the SUEs made this impractical.

The use of focus groups for the SUEs meant the notion of GSH could be explored and explained to ensure understanding of not only what was being asked but also its purpose. This allowed the SUEs to comment on what they would want and expect from self help materials.

In terms of implications for future research, the study continues to build on the evidence of the use and benefits of focus groups (Barr McConkey & McConachie 2003; Moonen, Kauppinen, Iyer*, et al*, PREPRINT. Logistically to not have recruited from existing groups might have seriously delayed the process and caused a number of issues for participants e.g., getting to an unfamiliar location, not knowing other participants, possibility of having no experience of the subject they are being consulted on. The use of established mental health service user groups meant that potential recruitment difficulties, which are a feature of intellectual disability research were avoided for this study. This approach can be criticised, for example the SUEs views may not have be representative of others accessing mental health services let alone the wider intellectual disability community. To mitigate this criticism, the groups that were recruited were located within two different mental health Trusts. Each of which had different models of mental health care for people with intellectual disability making it more likely a wider range of experience could be captured.

7.3 **Study 2**

The second study established acceptable reliability and validity of the SAINT. Many of the scales and approaches adapted from generic mental health research are not tested for their reliability and validity within the intellectual disability population. Prior to the use of generic scales for people with intellectual disability the potential limitations should be considered by clinicians and/or researchers, for example are the questions written and presented in a way that the respondent is able to understand.

The number of participants required to make any reasonable inference on the reliability and validity SAINT, meant it was necessary to recruit over a large geographical area. The initial recruitment strategy found difficulty in getting access to potential participants. This problem was evident across settings and was charactertised by an almost universal reluctance from staff and support workers to discuss possible participation in the research with the clients they knew. The reasons given for this included that the residents "lacked capacity" or that they would not ask because the residents "did not want to be involved". The use of intermediaries to recruit participants is well recognised (Nicholson, Colyer & Cooper, 2012) but fraught with problems. Although the mental health services approached were more supportive of research, many of the targeted clinical teams failed to identify any potential recruits. Although capacity was given as an issue by support staff for non participation; only five people from the 68 who put themselves forward to take part in the study were found to lack capacity during the consenting process. This was determined by the person's inability to understand the nature of the research when questioned. A number of clinical teams who were approached were supportive of the

research in principle but this failed to materialise into recruits with those put forward being rejected for not meeting the inclusion criteria. In terms of attrition once recruited participants from mental health inpatient services were the most likely to drop out. This was for a number of reasons including relapse and some who had been in hospital at recruitment dropped out on discharge or moved to other parts of the country where they were too far away to feasibly offer the intervention. .

To boost recruitment, housing and charitable organisations that had refused to engage locally were targeted at regional level. This offered some success with a number of organisations such as Mencap offering a platform to present the research before deciding whether to support participation from its staff and residents in supported housing. Other recruitment targets such as the local authority had long drawn out procedures. One London borough required two, one hour long face to face meetings, written answers to clarify questions on the protocol prior to presenting the application before a panel. An extraordinary decision was made with this particular application which was finally refused not on the quality of the proposal or concerns for participants, but because it was felt such an intervention was unnecessary as person centred planning was in place. In spite of the difficulty to recruit there were some unexpected benefits in terms of developing and improving networks that assisted recruitment in study 3.

To measure reliability and validity the SAINT was compared to gold standard depression and anxiety scales designed specifically for people with intellectual disability. The subsequent analysis demonstrated good to acceptable correlations of the SAINT with these measures and gave confidence that it reflected the construct of

concern, i.e., depression. Factor Analysis produced three factors relating to depression. Test-retest reliability was conducted to look at the consistency of responses when the measure was repeated a week later. This was to see if there was any fluctuation likely to occur due to irrelevant, chance factors when the measure was administered for a second time. The test retest was completed over a week which is an accepted period though there is no consensus on the optimum time frame for test retest and previous studies have varied the time between testing from 2 days to 2 weeks (Marx, Menezes, Horovitz*, et al*, 2003). The GDS-LD study performed test retest over the period of a day. Such a short period opens itself for criticism as a high correlation may be due to memory recall, or practice effects (Bartels, Wegrzyn, Wiedl*, et al*, 2010).

In conclusion, the results of study 2 gave confidence and reassurance that the SAINT materials were fit for purpose and helped to identify potential issues with the SAINT in practice e.g., the identification of items seemingly unrelated to depression. Given the encouraging results from the reliability and validity testing and the fact that the materials had been developed using SUE opinions the content was left unchanged, although the overall presentation of the SAINT materials did receive minor amendments following comments to improve accessibility.

7.4 **Study 3**

This study used a SCED method to evaluate effectiveness. To improve confidence in the SAINT the SCED process was replicated under the more demanding conditions using new SCED quality standards over a longer time period. The MRC 2008

guidelines endorse SCED as a legitimate experimental intervention. This can offer certain advantages over conducting a RCT e.g., being able to provide information on the variability of participant responses to an intervention in real time rather than estimating its effect across a whole group. Using a SCED had a number of benefits, which included being able to recruit individually but still maintaining experimental control. Using SCED methodology observations are recorded over time and evaluated using visual analysis. SCED using small numbers of participants is often criticised for not lending itself to statistical analysis, but the process of visual analysis allows a systematic approach where six areas are considered: variability, overlap, immediacy, consistency, trend and level. Although six items were used to visually analyse data, the most informative item in practice was the 'level' or mean score on the SAINT items. This methodology is in keeping with the MRC framework and allows a number of questions to be addressed, such as potential for effectiveness as an intervention or those issues that might normally be completed by a feasibility study such as recruitment, acceptability of the intervention or need to adapt the intervention prior to any potential RCT. SCEDs are also a cost effective way to provide evidence by identifying and defining those who are felt most likely to benefit from the intervention. This means that different groups can be targeted and be further divided into sub groups e.g., when used in people with intellectual disability and depression do people with mild or moderate intellectual disability have the same experiences and outcomes and do the materials need to be adapted or the approach changed to accommodate the different groups. All of this information is important to inform the design of any future RCT in terms of defining the study population. The decision to use a SCED design was considered in detail whilst

applying for ethical approval. Central to SCED is the withdrawal of treatment. In this case the SAINT was additional to treatment as usual and the withdrawal of the intervention in the 'no treatment' phases of the SCED were not considered likely to result in any harm to the individual who continued to receive routine care throughout the study including any prescribed medication, counselling, groups or activities. All potential participants were known to services and the treatment considered (GSH) was not a treatment considered hazardous or one that could not be reversed.

Using SCED methodology the following hypotheses were tested relating to feasibility, acceptability and effectiveness of GSH:

7.4.1 Feasibility

H1 The SAINT can be feasibly implemented in routine clinical services by recruitment across different care structures for people with intellectual disability and ***not*** *fewer than 70% of those approached will accept of offers of treatment.*

This hypothesis was broadly supported.

The SAINT is a manual based GSH approach. Although the intervention was delivered by nurses in this study there is no reason to suggest that it cannot be delivered by other groups such as qualified professionals, healthcare graduates, and experienced trainees who have access to training and supervision. An instruction manual, training, and supervision structures provided uniformity to the intervention. The SAINT was delivered weekly by a Nurse (the PI and one other). The sessions lasted between 15-30 minutes. The variation was to take into account individual

issues of understanding, reporting, and recall of participants. This format remained consistent within all of the study settings. In terms of support between sessions this appeared to vary by study location, e.g., within inpatient services, the intervention was more likely to be seen as part of the treatment programme. This meant that it was more likely that participants would receive the support and guidance requested, whereas those at out patients were more likely to use the SAINT privately or not seek support. For those who wanted to participate more fully but who lacked support, the potential impact of the intervention may not have been fully realised. In practice, regardless of their level of support, there was some variation as to how the SAINT was used. Some participants identified and recorded their feelings using numbers in the diary as suggested in the training manual; whilst others used the diary to record their feelings and coping strategies in more detail, by producing a narrative. To introduce consistency and encourage support training for the SAINT was provided for both participants and those supporting them. Training was also offered to others close to the person such as carers or other residential and hospital staff so that support was more likely to be maintained. To reinforce the need for consistency of the approach a training manual was also provided to reinforce the process. Originally the training was to be delivered over a day, however problems with services releasing staff to both internal and external venues meant that training was often completed in the workplace prior to starting the SAINT. A number of organisations that had originally agreed to send people on training later declined to be a part of the study. The reason often stated was that weekly visits would be too disruptive to the person's routine. Whether the person was asked if they wanted to

take part or actually felt their routine would be disrupted is not clear or indeed whether initial interest was mostly those of the organisation.

Recruitment took place at inpatient, outpatient and residential settings. Of the 22 who were identified, seven were withdrawn by the clinical team or house staff prior to or in the baseline phase. This left 15 participants, 12 (80%) of whom completed all four phases whilst the other three had completed at least one baseline and intervention phase. If those who were withdrawn from the study are included this figure drops to 54.5%. The hypothesis, that fewer than 70% of those approached would refuse treatment is partly supported.

There were lessons learned at all stages of the recruitment process. As noted earlier, a lack of expertise within one local committee saw members confusing the intervention with person centred planning with the result that the study was not approved. A number of local teams were approached and supportive but were unable to provide participants. The issue of access during the pilot was not as problematic as it was in the reliability study. This may have been due to contacts and networks that had been established in the two earlier studies. However retention during the pilot proved to be more of a problem. This may have been due to the expectation to participate over a period lasting between 16-22 weeks; as opposed to a single meeting or two meetings over the course of a week in the reliability study. In the development study there were no drop outs. This may have been due to the fact that all recruits were engaged in familiar places and within an already established structure. This variation in recruitment is complex and a number of factors require consideration including the methodology used, the expected role of participants,

barriers to accessing potential recruits and definition of the population e.g., if all those with a diagnosis of affective disorders (F30-39), are included rather than a single diagnosis of depression the numbers of those who are eligible to participate will increase.

Identifying and recruiting those not known to intellectual disability services living independently is a challenge that affects the generalisability of findings to both the intellectual disability and wider population. A future feasibility study for a RCT is needed to test recruitment further in the light of these findings. This would also enable us to test the conclusions contained within this thesis.

As with all unfunded studies another issue that may have affected recruitment is being unable to remunerate participants for their time. This would need to be tested and costed into any future study.

7.4.2 Acceptability H2

H2: The SAINT is acceptable to participants as demonstrated by <20% discontinuation from treatment and reported satisfaction with the process at the end of treatment

The acceptability of the intervention was assessed by retention rates and by examining user feedback from the different study settings.

Of the 22 participants who agreed to take part, seven were withdrawn. For two of these cases an additional nurse had been trained to deliver the SAINT, but unfortunately was unable to continue after an initial session. In the remaining five, reasons were ill health and participants changing their mind. All of these withdrew

before the intervention phase of the SCED. It may be that the design plays some part in this if people see the intervention and materials as an incentive but are not prepared to wait for it to be introduced. To try to prevent this, at each session participants were orientated to the phase they were currently in and what to expect in subsequent weeks. In all 12 people completed the SAINT in part 1 and a further three in part 2. From part 1, three (20%) participants who had completed an intervention phase discontinued treatment, whilst there were none from part 2 (0%), so overall 3/18, (16.7%), discontinued form the intervention. Of those completing the intervention phases over 86% of sessions were attended supporting the first part of the hypothesis.

Results from the framework analysis suggest that the majority of those who used the intervention offered positive feedback from their experience. The process was validated by the critical comments and constructive criticism that showed evidence of independent thought, demonstrating choice and not being suggestible to the comments of the interviewer. One participant produced written reports using words and pictures about how people could benefit from the SAINT, however a couple of participants did find using it slightly complicated. Again this highlights the need for adequate support especially for those with lower levels of functioning. Others however wanted more in the manual e.g., a personalised daily planner and information pages on mental health. The acceptability of the SAINT would benefit from further exploration of how to address the support needs of participants in more detail. Another issue was the accessibility of the materials not only to see how they were understood but also to see if any adaptations are needed to deliver the SAINT to people with intellectual disability with specific needs e.g., those with ASD or

sensory impairments. Overall the majority of participants reported the use of the SAINT favourably accepting the final part of the hypothesis.

7.4.3 Effectiveness H3

H3: The SAINT intervention is effective in terms of reductions in mean scores on measures of depression and anxiety (using the GDS-LD (Cuthill, Espie & Cooper, 2003), GAS-ID) (Mindham & Espie, 2003) and the SAINT); and that a reduction in mean scores can be replicated in 1-3 participants who have previously received the intervention.

To examine mean scores, measures were administered at both the baseline phases then at the intervention phases. The SAINT and its training manual was not given until the first intervention phase and removed from participants post intervention. The weekly visits still took place during the baseline phases with the SAINT being replaced by general conversation, whilst measures were taken. It is suggested that between 2-4 replications are required to have confidence in the experimental control and treatment effectiveness of any study (Barger-Anderson, Domaracki, Kearney-Vakulick*, et al*, 2004). To test the findings from part 1 the SAINT was repeated in two people with depression and anxiety who met the criteria set out in H3. To offer further confidence to the findings additional criteria were also stated and/or employed by the introduction of:

- A gap between ABAB at time 1 and time 2
- An extended baseline to guard against carry over effects (A)
- An increase in the length of phases (BAB). This meant that effectively the two participants completed 4 baseline and intervention phases

Three people in part 1 of study 3 achieved decreased mean scores during both intervention phases across all three measures used, with another three showing improvement on the intervention phases in two of the three measures. More importantly these results (improvement two-three measures) were replicated for two participants under longer more stringent conditions. The use of quality standards allowed replication and provided a framework in which results can be analysed and interpreted. With decreases in mean scores in part 1 and their replication in 2 cases in part 2, H3 is accepted.

7.5 **Strengths and limitations**

The lack of evidence for GSH being used for people with intellectual disability provided a number of additional research challenges. To get the opinion and consensus of different groups a common methodological approach would have been preferred. However the need to make the process accessible for the participants with intellectual disability and ensure their opinions were accurately reflected meant the two groups needed to be engaged differently i.e., email questionnaires and focus groups. Prior to the research participants and those supporting them had little or no

knowledge of GSH. This made explanation difficult at times as some of the components or philosophies of GSH are similar or to approaches used by those supporting people with intellectual disability such as person centred planning and the use of homework as part of treatment or education activities. These philosophical similarities did directly impact on the recruitment strategy with some people wrongly convinced that it was something they were already doing. The use of qualitative methodology in intellectual disability research is still in its infancy. As a result there is limited evidence of its effectiveness in this group. There is however a growing literature on the practicalities of engaging people with intellectual disability which include guides on communication, how to make materials and media accessible, how to set up groups and protocols consisting with best practice when using qualitative methods with this group (Nind, 2009). A number of studies and guides were considered when developing the SAINT including the IAPTs guidance on GSH (Improving Access to Psychological Therapies, 2010).

7.6 **Advances and future directions**

To date the SAINT has been disseminated at a number of conferences, academic forums and team meetings locally, nationally and internationally. This has been useful in terms of feedback that could be added to that received from participants, carers and support staff. A number of people have seen additional utility in the SAINT as a method to engage with people and promote positive mental health as well as a GSH intervention.

However, proof of its utility will ultimately be determined by its implementation in practice and in future research to develop an evidence base around acceptability and effectiveness of the intervention. Following the MRC Framework recommendations, the next step would be a multi centre RCT to further establish effectiveness compared to other treatments also used in mild depression. This larger study might test the SAINT on a more defined population i.e., just those with depression, and the multi centre approach will allow recruitment over a wider geographical area to be tested. The location of delivery e.g., a GPs surgery or out patients and estimates of the cost effectiveness compared to other treatments offered can also be addressed. Plans are underway to apply for research funding; whilst the SAINT manual and training are being amended and available as a result of comments received during the course of this study. The revised materials are to be published as part of a series on psychological therapies with the intention that it is available at a low cost and a CD containing not only the manual and training materials but also additional resources around mental health promotion and goal setting. Although additional materials were not used in this study, there were suggestions that these could be useful to offer information have a visual representation and chronology for targets. In this study those facilitating the intervention were all experienced in the mental health care of people with intellectual disability. Training in the use of the additional materials with instruction will help less experienced facilitators.

7.7 **Summary**

This thesis has described how the SAINT was developed, tested, piloted and reviewed. The study has raised awareness of GSH as an intervention for people with intellectual disability through a number of publications and presentations. These have showcased it as a potentially viable and valid treatment option for this group. This is in line with the MRC 2008 guidelines to share research progress at key points. Publications so far include a report on the development of the SAINT, (Chaplin, Craig & Bouras, 2012) and a paper on its reliability and validity (Chaplin, Chester, Tsakanikos*, et al*, 2013). A number of other publications have mentioned it in practice (Chaplin & Hardy, 2012) and as an aid to mental health promotion (Chaplin & McCarthy, 2013). The SAINT has also been compared to other measures of anxiety and depression with regards to gender, separate from this work and post development (Chester, Chaplin, Tsakanikos*, et al*, 2013).

This study has been conducted at a time when there is a general lack of awareness within health services of the needs of people with intellectual disability (Michaels, 2008). This group are often overlooked and many have difficulty in accessing health services (Disability Rights Commission, 2006). There is currently little understanding as to the efficacy of psychological treatments in people with intellectual disability. The poor evidence base is further confounded by exclusion and difficulty in accessing services (Hassiotis, Serfaty, Azam*, et al*, 2011). This study begins to addresses the lack of availability of low-level psychological treatments appropriate for people with intellectual disability, in particular GSH where there is no previous published evidence for this group. The need for specialist

GSH has been recognised by the National Institute for Clinical Excellence, (2012) and more recently advocated this type of treatment for people with ASD and highlighted research into GSH should be a priority. The lack of access to appropriate mental health care and/or interventions for people with intellectual disability can impact negatively on individuals in a number of ways including deterioration of mental state, placement breakdown and escalation into a crisis situation. The SAINT is the first GSH study published that addresses these points and has been developed and piloted specifically for people with intellectual disability and included people with ASD. The SAINT has offered people not only an understanding of how things affect their mental well being but also a way to play a role in maintaining good mental health by involving them rather than just using them to reported outcomes. The study involved service users from the outset. This is an essential part of the process at all levels and should have a measurable benefit (Doel, Carroll, Chambers*, et al*, 2007). User involvement can be achieved in a number of ways e.g., are they leading the study, a part of the study or being consulted on the academic rigor of the investigation. Also do participants get satisfaction through participation either thorough a sense of purpose or increased self esteem or it may be some form of remuneration. Morrow, Boaz, Brearley*, et al* (2012), classified four levels of service user involvement in nursing and healthcare research, these are consultation, contribution, collaboration and control. The aim of the four Cs was to demonstrate the role of service users across the continuum of research investigation. The first stage is professional led research; the second and third stages incorporate partnership working, with fourth stage being user led research. Participation aside, service users were consulted as part of the Patient and Public Involvement process

prior to ethical approval future collaboration is planned from SUE after this study in terms of writing about and publishing their experiences.

The final study was able to demonstrate that people with intellectual disability can use GSH techniques and report benefit from them. As well as user acceptability, the SAINT also showed its potential for future use in clinical practice as a viable alternative to CBT for people with intellectual disability with mild depression and anxiety. It is more accessible and less expensive than a number of other person centred therapies. GSH puts the person at the centre of their treatment and does not encourage dependence, whilst still offering support and gives the person control to make decisions whilst being supported. The availability of free materials suits the fact that a range of workers with minimal training can administer GSH, whereas other treatments require qualified therapists. Saying this there should be access to supervision for workers as with any psychological based treatment where there is any potential for harm (Department of Health, 2008).

As well as identifying GSH as a legitimate intervention for people with intellectual disability it has also raised a number of ethical and methodological issues when conducting research with people with intellectual disability. One of the big issues encountered was the question of access to potential participants is not a simple one, as ethically there needs to be safeguards where vulnerable adults are involved, however there are no local systems or policies currently in place to identify those who might want to participate who are not currently accessing mental health services. However the denial of rights, choice and inclusion is contrary to current UK intellectual disability policy. There needs to be mechanisms put in place that

gives the person choice and/or informing them of the approach but that also affords them protection from exploitation. Towards the end of this study such a mechanism called ‘Consent for Consent’ was introduced within local mental health services. This initiative not only asks people if they would be interested in an approach to take part in future research but also allows them to stipulate under what conditions they wish to be approached and for what type of research.

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Self-help books 'treat depression' http://www.bbc.co.uk/news/health-21083458.19 January 2013, Last updated at 00:42

Self Help leaflets, Leaflet Search Request http://www.ntw.nhs.uk/pic/selfhelp

7.8 Appendix 1 Validity of intellectual disability outcome measures

Name	Items scoring	Item construction and review	Content analysis Face validity	Discriminant validity (DV)	Criterion validity	Content validity	Test retest two tailed And inter rater reliability	Internal consistency	Sensitivity and specificity
GAS-ID Anxiety in people with ID	High score: 54 27 items in 3 sections: Worries (10), phobias (9) and physiological (8) Scoring 2 always, 1 sometimes 0 never. Some items reversed	2 focus groups each lasting 45 minutes, with 4 participants and 1 moderator (moderate / mild ID). Items informed from review of existing schedules	42 item pool constructed by 2 authors then 5 psychologists and 4 trainees 3 samples 1. anxiety with ID 2. No anxiety with ID 3. Anxiety without ID.	The 2 ID groups used. To see if measure discriminated within the three groups. ANOVA found DV in anxiety v non anxiety groups in terms of reported anxiety. (F=51.99; df = 2; p<0.001). Scheffe post hoc also sig difference p=<0.005.	Non ID group for (17 per group needed) aimed for 28 males 26 females obtained GAS-ID was compared to BAI (n=19 people non ID), Spearmans rank order correlation 0.72 and 0.75 with overlapping items deleted. 6 GAS items similar to 8 BAI items.	None of the 20 retained items was assigned a score of 0 (or 2 if reverse rated) by more than half of the ID depression group, *Concurrent validity* Measured physiological symptoms by arousal (pulse). Anx group had higher pulse rates mann-whitney u test = 11.5, p=0.054	(n=17) 4 weeks interval pearson product moment correlation r= 0.953; p<0.0001,	0.96 (n=35) ID group. Split half correlation total scale score 0.93 Cronbach's alpha 0.92, worries, 0.8 phobias and 0.90 physiological	
Glasgow Depression Scale-LD Depression in ID	Review of existing diagnostic schedules (ID and non ID) to represent breadth of symptoms. Originally 28 items in total. Focus groups		Pilot completed with 3 people with ID and depression. 2 m and 1f and 3 people with ID and no depression 2 m and 1f (6-2). Groups completed draft	3 groups ID and depression. ID no depression and no ID or depression. data said to discrimination between the depression and non-depression	27 participants in the non-learning-disability depression group completed both the GDS–LD and the BDI–II. Data were analysed using		(n=38) (r=.97; P>0.001) and r=.94 (n=18) just ID and depression	Alpha was x = 0.90 for the total scale ((the learning-disability depression group only was 0.81, (n=18)	GDS–LD score of 15 optimal if the intention is to exclude those who are not depressed (specificity 100%). sensitivity (90%). to avoid false- positive

Name	Items scoring	Item construction and review	Content analysis Face validity	Discriminant validity (DV)	Criterion validity	Content validity	Test retest two tailed And inter rater reliability	Internal consistency	Sensitivity and specificity
	Groups audiotaped and transcribed. Words describing emotions were logged and counted. Most frequently occurring words made up adapted questions		and 8 questions were removed due to being too hard to understand, reacting negatively by shouting and 1 did not discriminate	variance (F=444.45; d.f. =2, P>.001) and Scheffé post hoc test p>0.05) significant difference between the non-ID depression group similar ID and depression significantly higher than those with ID and no depression	signifying excellent criterion validity. Retaining only those items that have no overlap with the BDI–II (items 5, 16–20) this correlation remained strong (r=.84; P>0.001).				detect individuals with depression to 96%, decreasing specificity to 90%. a cut-off of 10 would detect 100% but with specificity of 68%. To detect depression, without wrongly identifying those not depressed, 13 advised as the cut-off point for screening purposes.
PAS-ADD Checklist	life-events checklist and 29 symptom items scored on a four-point scale				Compared with psychiatrists notes (n=59)		inter-rater agreement, Spearman rank correlations between the TT all above 0.55. 0.79 Individual item agreements were calculated Cohen's Kappa. The mean Kappa was 0.42. This low value is an indication of the problem of obtaining	Scale Affective/neurotic 0.84 (20) Organic 0.63 (6) Psychotic 0.51 (4) Total.0.87 (27) Cronbach's Alpha 0	

Name	Items scoring	Item construction and review	Content analysis Face validity	Discriminant validity (DV)	Criterion validity	Content validity	Test retest two tailed And inter rater reliability	Internal consistency	Sensitivity and specificity
							reliable scores using untrained raters and no glossary of symptom definitions to guide the ratings.		
CANDID is a needs assessment instrument for adults with ID and mental health problems.		First draft Focus groups of service users (n=8), informal carers (n=7) and staff (n=9) identified areas of needs relevant to people with ID and mental health problems. The first draft was commented on by health and social services professionals (n=24) from this the second draft was developed. .	Users (all abilities) n =45) and carers scored each need area item according to its relevance, and to suggest any additional items CONSENSUAL VALIDITY Forty-five experts (81.8%) responded to the questionnaire. 5% rated the instrument's structure as low for `helpfulness of anchor points' and `ease of use.' The draft instrument's language was rated as `inappropriate' by 20%		compared with the total DAS and GAF scores. Spearman's r correlation coefficients were -33 (p>0.05) and -47 (p>0.01) respectively, high concurrent validity.	45 users and carers approached responded to the questionnaire. a total score for each need item was calculated and all items were ranked according to this score. The highest scoring items were accommodation and self-care, while the lowest were autistic features and telephone use.	For interrater reliability the intraclass coefficients were 0.93 for user, 0.90 for carer and 0.97 for staff ratings. For test-retest reliability they were 0.71, 0.69 and 0.86 respectively. No evidence of relative bias between the two time complete agreement		

Name	Items scoring	Item construction and review	Content analysis Face validity	Discriminant validity (DV)	Criterion validity	Content validity	Test retest two tailed And inter rater reliability	Internal consistency	Sensitivity and specificity
SAINT	Dichotomous yes or no, no threshold yes score triggers use of coping mechanisms	No gold standard. To establish construct validity this study requires participants to answer the 10 questions from the SAINT (which require a categorical judgment i.e., yes or no) Please see criterion validity to see SAINT, correlated against the GDS-LD, GHQ-12, GAS-ID.	Delphi, SALT review, review from peers		(n=36) GDS-LD 0.770 GAS-ID worries 0.644	The SAINT's content and consensual validity was developed from a service user and Delphi expert consultation. It was also reviewed by the local Speech and Language Therapy team	(*n*=18) Pearson .907	(*n*=36) Cronbach alpha 0.869	

Sensitivity refers to the ability of the scale to identify correctly all those who belong to a particular group (in this case people with depression) and specificity refers to the likelihood of people out with the group (those without depression) being wrongly included.

7.9 Appendix 2 Ethical Approval

Bexley & Greenwich Research Ethics Committee
South London REC Office (4)
Ranken House
Queen Elizabeth Hospital
Stadium Road
Woolwich
London
SE18 4QH

Telephone: 0208 836 6740
Facsimile: 0208 836 4862

20 August 2008

Mr Eddie Chaplin
Strategic Development Officer
Estia Centre
66 Snowsfields
London SE1 3SS

Dear Mr Chaplin

Full title of study: **The role of a self-assessment and intervention package, (SAINT); in improving general mental health outcomes for people with intellectual disabilities and depression.**
REC reference number: **08/H0809/43**

Thank you for your letter of 08 August 2008, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Sub-Committee of the REC held on 20 August 2008. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). The favourable opinion for the study applies to all sites involved in the research. There is no requirement for other Local Research Ethics Committees to be informed or SSA to be carried out at each site.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements.

7.10 **Appendix 3 Ethics substantial amendment**

NHS
National Research Ethics Service
NRES Committee London - Bromley
South London REC Office (5)
Ranken House
Queen Elizabeth Hospital
Stadium Road
Woolwich
London
SE18 4QH

Tel: 0208 8366740
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07 April 2011

Mr Eddie Chaplin
Strategic Development Nurse
South London and Maudsley NHS Foundation trust
Estia Centre 66 Snowsfields
London
SE1 3SS

Dear Mr Chaplin

Study title: **The role of a self-assessment and intervention package, (SAINT); in improving general mental health outcomes for people with intellectual disabilities and depression.**
REC reference: **08/H0809/43**
Amendment number: **1**
Amendment date: **21 March 2011**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

There were no ethical issues raised

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Glasgow Anxiety Scale- ID		
Lay protocol		
Interview Schedules/Topic Guides	1	
Participant Information Sheet	1	
Protocol	3.5	
Notice of Substantial Amendment (non-CTIMPs)	1	21 March 2011
Covering Letter		21 March 2011

7.11 **Appendix 4 Information and consent forms**

CONSENT FORM - A self help pack to help people with learning disabilities with mental health problems Study.

To let us know whether you would like to take part in our research project we would like you to fill in this form.

Your name is? _____

Have you looked at the information sheet? YES NO

Have you talked to someone about the project? YES NO

Do you understand what the project is about? YES NO

Do you understand that it may become necessary to inform a professional if you or someone else is not safe? YES NO

Would you like to take part in the project? YES NO

Would you like to be sent a summary of the results? YES NO

I the undersigned have read the information about this study and give my consent to take part. I understand that I can withdraw at any time and that this study might not help me but may help other people.

Volunteer signature…….Date…….

I confirm that the volunteer above has received the information regarding the study and has provided informed consent.

Witness signature……..Date…….

INFORMATION SHEET

Can a self help pack help people with learning disabilities who have problems with distress.

Why is the research being done?

Some people with learning disabilities get little support at home. This research is about a self help book called the SAINT.

The SAINT is to help people with learning disabilities when they get upset or feel distressed.

The SAINT will help people to recognise feelings e.g. when they are upset or feeling low or anxious.

The SAINT also has a section on coping strategies to help people feel better.

We have already talked to people with learning disabilities and people who work in mental health services to help make the SAINT.

What will I be asked to do?

The people doing this research come from your local learning disabilities or mental health services and they will ask you if you would like to take part.
The study is in 4 parts

This will mean being asked questions about your feelings over 16 weeks. We will need to know other things about you such as your age, what area you are from. If you are unable to answer these questions we would ask you if it is OK to get them from your notes.
There are no right or wrong answers because it is about how you feel.

For part of this time you will also use the SAINT book.
Part 1: The first 4 weeks you will just answer a questionnaire about how you feel.

If you have not seen the SAINT before then some one will go through this with you as well on the first visit.

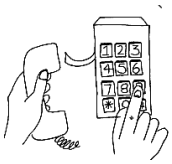
Part 2: The next 4 weeks you would do the SAINT; before you do this you and/or those supporting you would have had some training in how to use it.

You will keep doing the questionnaire as well.

We will also give you a small training book to help.

Part 3: The next 4 weeks we will ask you to stop doing the SAINT and just ask you to do the questionnaire.

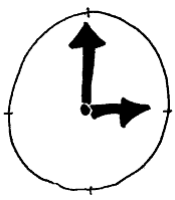
Part 4: The final 4 weeks you would do the SAINT and the questionnaire.



If there are problems you will be able to phone the research team or arrange for a time for them to call you.

The questionnaires will tell us if people feel better when they are doing the SAINT or when they are not doing it.

Whether you choose yes or no to taking part, your current services and treatment will not be affected.



Answering the questions will take between 10-15 minutes.

When you use the SAINT you can do this with someone who supports you or on your own. There will be a training book and DVD to help people until they are used to it

What will happen if there is a problem?

If you are worried about the research we would like you to tell us.

You can then choose to stop at any time.

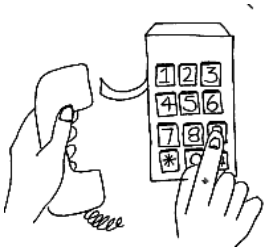
If you find any of the questions upsetting we will stop the interview or group. If it is an interview we will ask you if you would like us to tell anybody about how you are feeling. If you would like we could tell your carer or someone who supports you. If we think it is important to tell someone, we will discuss this with you and explain the reasons why.

Who will be able to see my results?

Your results will be put onto a computer. Your name will not be on the computer. The research team will be the only people who will see the results.

Do I have to take part in this research?

You do not have to take part in this research. If you do not want to take part in this research or you want to stop answering the questions or doing the tests that is fine. It will not affect your care in any way



If you want to ask any more questions about this research you can contact Eddie Chaplin on 0203 228 9743 or ask your carer to do so for you. THANK YOU

Note to carers or people supporting participants

The aim is for participants to feel they want to take part in the research, at all times the person has the right to withdraw, request a break or to ask if they do not understand. A person can do this at anytime whether they have originally consented or not.

Taking part in this research I no way will affect anyone's current services.

During interviews
If you feel the person your supporting is becoming distressed or does not understand, please interrupt so there is the opportunity for the situation not to escalate. If at any time you feel the person may benefit from a break please interrupt to ask the person.

During the research period
If you feel at any time the person is being unduly stressed by participating or as requested to leave the study, please contact Eddie Chaplin on 020 3228 9743

If you are at all concerned about the research please contact
Dr Jane McCarthy, York Clinic, Guys Hospital, London SE1 3RR or leave a message on 020 7188 0201

7.12 **Appendix 5 The Saint GSH Manual v.2.1 (A4 Version)**

Self-**A**ssessment and **Int**ervention Pack: **SAINT**

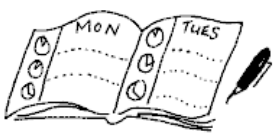
Helping people help themselves

This book is about helping people feel good.

You can use the book to record your feelings

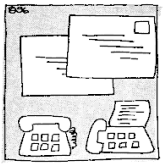
This book will help you know when you are feeling upset

This book will let professionals know when you are feeling upset



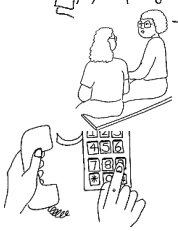
The book has a diary. You can write on the diary to show how you feel.

Name



Address

Things I do in the daytime



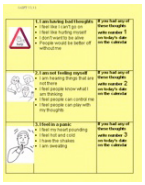
People who are important to me

Important phone numbers

Important dates

How to use this book
Try to look at this book once a day

When you open the book, look at the feelings list first. Then follow the instructions



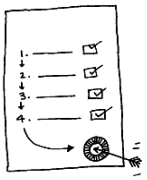
The feelings chart

Each day you should think about how you are feeling.

If you feel OK then write OK on the

diary.

If you feel poorly look at the feelings list.



Every feeling has a number.

If any of the feelings on the list describe how you feel write Feelings Chart

	**1. I am having bad thoughts** • I feel like I can't go on • I feel like hurting myself • I don't want to be alive • People would be better off without me	If you had any of these thoughts write number **1** on today's date on the diary
	**2. I am not feeling myself** • I am hearing things that are not there • I feel people know what I am thinking • I feel people can control me • I feel people can play with my thoughts	If you had any of these thoughts write number **2** on today's date on the diary
	**3. I feel in a panic** • I feel my heart pounding • I feel hot and cold • I have the shakes • I am sweating	If you had any of these thoughts write number **3** on today's date on the diary

	**4. I find it difficult to do things** • I am losing interest in things • I don't feel like going out • I can't be bothered to change my clothes • I have stopped activities and/or going out	If you had any of these thoughts write number **4** on today's date on the diary
	**5. I am having problems sleeping** • I have trouble getting off to sleep • I have trouble waking up • I keep getting up during the night • I feel tired all the time	If you had any of these thoughts write number **5** on today's date on the diary
	**6. I feel down today** • I feel sad • I feel worried • I feel tense • I feel stressed	If you had any of these thoughts write number **6** on today's date on the diary

	**7. I don't feel in control** • I am worried about my temper • I feel angry • I am worried about drinking too much and/or drugs	If you had any of these thoughts write number **7** on today's date on the diary
	**8. I feel bad about myself** • I feel people do not like me • I feel my life will not get any better • I feel everyone hates and ignores me • I keep letting people down	If you had any of these thoughts write number **8** on today's date on the diary
	**9. I feel emotional** • My mood keeps going up and down • I feel heartbroken • I feel unwell • I am in pain	If you had any of these thoughts write number **9** on today's date on the diary
	**10. Looking after myself** • I am not taking good care of myself • I am not eating well • I am not washing or bathing I cannot concentrate on things	If you had any of these thoughts write number **10** on today's date on the diary

If you have any of these feelings, write the number in the diary.

If you feel OK then write OK in the diary

Diary FeelingsWeek 1:

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

If you have written a number in your diary go to the coping with feelings list

The Coping Chart

This chart has a list of things you can do that might make you feel better

There are ten coping ideas in the chart

Each has a number

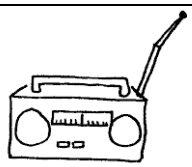
Because we can do things different ways we have put some examples under the ten coping ideas

If you do any activities from the lists write the number for that activity in your diary

You should look at the SAINT book at least once a day

Coping strategies chart

	**11. Talking about it** • Talk to someone about my problems • Talk to someone I know • Ring someone like the Samaritans • Speak to someone in your team	If you did any of the activities then write the number **11** on today's date on the diary
	**12. Positive thoughts** • Remember how well I did before • Tell myself I can cope • Tell myself I am strong	If you did any of the activities then write the number **12** on today's date on the diary
	**13. Exercise** • I will do some exercise to make myself feel better • I will go for a walk/run • I will go to the gym • I will ask someone to play a sport maybe tennis	If you did any of the activities then write the number **13** on today's date on the diary
	**14. Go out** • I will go out somewhere to make myself feel better • I will go and see friends • I will go and do something like the cinema or shopping	If you did any of the activities then write the number **14** on today's date on the diary

	**15. Relaxation** • I will do some relaxation exercises • I will do deep breathing • I will listen to a relaxation tape • Use nice smell (aromatherapy, scented candles)	If you did any of the activities then write the number **15** on today's date on the diary
 	**16. Listening to music or watching TV** • I will go and listen to music • I can play music, I will do that • I will watch TV • I will watch a DVD or video	If you did any of the activities then write the number **16** on today's date on the diary
	**17. I will do a hobby** • I like collecting coins • I like to organise things music collection • I like gardening • I have a different hobby I enjoy	If you did any of the activities then write the number **17** on today's date on the diary
	**18. Play games** • I will play cards with others or on my own • I will play a board game like snakes and ladders • I like to play video games • I like games like snooker and pool	If you did any of the activities then write the number 18 on today's date on the diary

	**19. Other things I enjoy** • I like word searches • I like puzzles • I like doing things on the computer I will write in my diary	If you did any of the activities then write the number **19** on today's date on the diary
	**20. Keep Busy** • I like drawing • I like colouring things • I like to go out and do things • Look in the shops	If you did any of the activities then write the number **20** on today's date on the diary

Remember to look at this pack everyday

Remember to write your feelings and coping in the diary

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

NOTES:

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

NOTES:

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

NOTES:

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

NOTES:

7.13 **Appendix 6 The Saint Training Guide**

Self-**A**ssessment and **Int**ervention Pack:

SAINT

Helping people help themselves

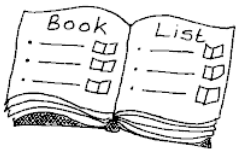
For More Info please contact:

Eddie Chaplin
Estia Centre
66 Snowsfields
London
SE1 3SS
0203 228 9743

eddie.chaplin@slam.nhs.uk

How to use the SAINT book

This let tells you how to use the SAINT book

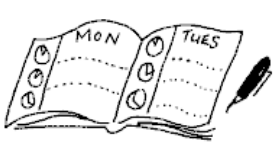


The SAINT book is about helping people feel good.

You can use the SAINT book to record your feelings

This SAINT book will help you know when you are feeling upset

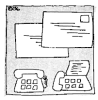
The SAINT book will let other people know when you are feeling upset



The SAINT book has a diary. You can write on the diary to show how you feel.

The first page is to write about you

Name



Address

Things I do in the daytime

People who are important to me

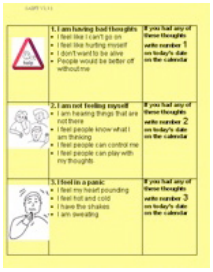
Important phone numbers

Important dates
How to use this SAINT book

How to use the SAINT book

The SAINT book as two main parts

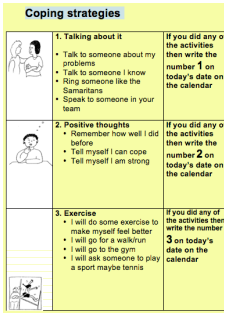
1. Feelings
2. Coping with Feelings



The feelings part comes first

Part 1 has a list of feelings that might be happening to us

And is followed by the coping part of the SAINT book



Part 2 is a list of things we can do to help us cope

You should look at the SAINT book at least once a day

When you open the SAINT book, look at the feelings list first.

There are ten feelings in the list

Feelings can be hard to describe

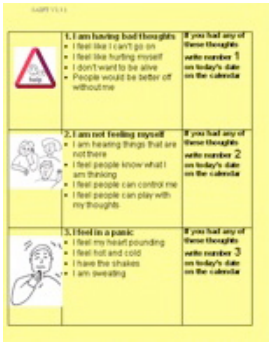
Because we describe feelings differently we have given some examples

Each of the 10 feelings has a small list to show what we mean

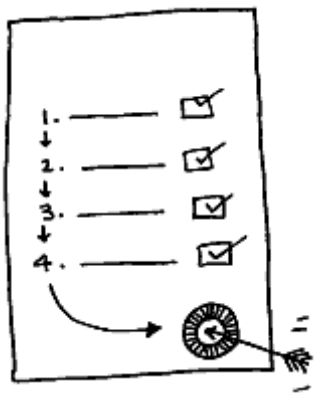
The feelings list

Each day you should think about how you are feeling

If you feel OK then write OK on the diary.



If you feel poorly look at the feelings list.



Every feeling has a number.

If any of the feelings on the list describe how you feel write the number in the diary.

Feelings Chart

	**1. I am having bad thoughts** • I feel like I can't go on • I feel like hurting myself • I don't want to be alive • People would be better off without me	If you had any of these thoughts write number **1** on today's date on the diary
	**2. I am not feeling myself** • I am hearing things that are not there • I feel people know what I am thinking • I feel people can control me • I feel people can play with my thoughts	If you had any of these thoughts write number **2** on today's date on the diary
	**3. I feel in a panic** • I feel my heart pounding • I feel hot and cold • I have the shakes • I am sweating	If you had any of these thoughts write number **3** on today's date on the diary

	**4. I find it difficult to do things** • I am losing interest in things • I don't feel like going out • I can't be bothered to change my clothes • I have stopped activities and/or going out	If you had any of these thoughts write number **4** on today's date on the diary
	**5. I am having problems sleeping** • I have trouble getting off to sleep • I have trouble waking up • I keep getting up during the night • I feel tired all the time	If you had any of these thoughts write number **5** on today's date on the diary
	**6. I feel down today** • I feel sad • I feel worried • I feel tense • I feel stressed	If you had any of these thoughts write number **6** on today's date on the diary

	**7. I don't feel in control** • I am worried about my temper • I feel angry • I am worried about drinking too much and/or drugs	If you had any of these thoughts write number **7** on today's date on the diary
	**8. I feel bad about myself** • I feel people do not like me • I feel my life will not get any better • I feel everyone hates and ignores me • I keep letting people down	If you had any of these thoughts write number **8** on today's date on the diary
	**9. I feel emotional** • My mood keeps going up and down • I feel heartbroken • I feel unwell • I am in pain	If you had any of these thoughts write number **9** on today's date on the diary

	**10. Looking after myself** • I am not taking good care of myself • I am not eating well • I am not washing or bathing I cannot concentrate on things	If you had any of these thoughts write number **10** on today's date on the diary

If you have any of these feelings, write the number in the diary. If you feel OK then write OK in the diary

Diary Feelings
Week 1:

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

If you have written a number in your diary go to the coping with feelings list

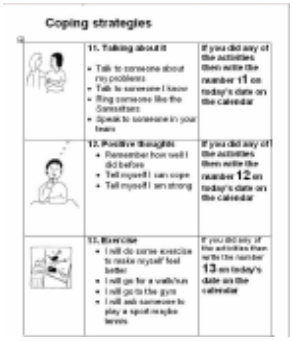
The Coping Chart

This chart has a list of things you can do that might make you feel better

There are ten coping ideas in the chart

Each has a number

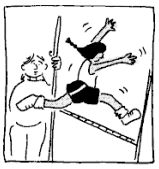
Because we can do things different ways we have put some examples under the ten coping ideas



If you do any activities from the lists write the number for that activity in your diary

You should look at the SAINT book at least once a day

Coping strategies chart

	**11. Talking about it** • Talk to someone about my problems • Talk to someone I know • Ring someone like the Samaritans • Speak to someone in your team	If you did any of the activities then write the number **11** on today's date on the diary
	**12. Positive thoughts** • Remember how well I did before • Tell myself I can cope • Tell myself I am strong	If you did any of the activities then write the number **12** on today's date on the diary
	**13. Exercise** • I will do some exercise to make myself feel better • I will go for a walk/run • I will go to the gym • I will ask someone to play a sport maybe tennis	If you did any of the activities then write the number **13** on today's date on the diary
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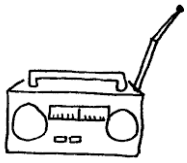
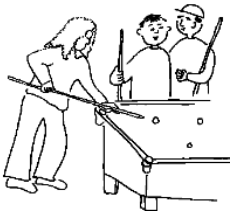
	**15. Relaxation** • I will do some relaxation exercises • I will do deep breathing • I will listen to a relaxation tape • Use nice smell (aromatherapy, scented candles)	If you did any of the activities then write the number **15** on today's date on the diary
 	**16. Listening to music or watching TV** • I will go and listen to music • I can play music, I will do that • I will watch TV • I will watch a DVD or video	If you did any of the activities then write the number **16** on today's date on the diary
	**17. I will do a hobby** • I like collecting coins • I like to organise things music collection • I like gardening • I have a different hobby I enjoy	If you did any of the activities then write the number **17** on today's date on the diary
	**18. Play games** • I will play cards with others or on my own • I will play a board game like snakes and ladders • I like to play video games • I like games like snooker and pool	If you did any of the activities then write the number 18 on today's date on the diary

	**19. Other things I enjoy** • I like word searches • I like puzzles • I like doing things on the computer I will write in my diary	If you did any of the activities then write the number **19** on today's date on the diary
	**20. Keep Busy** • I like drawing • I like colouring things • I like to go out and do things • Look in the shops	If you did any of the activities then write the number **20** on today's date on the diary

Remember to look at this pack everyday

Remember to write your feelings and coping in the diary

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**

Wednesday	**Sunday**
Thursday	**NOTES**

Next are some examples of

How to use your diary

Here are some examples

EXAMPLE 1

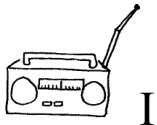
John felt upset so he looked at his SAINT SAINT book. Looking at the SAINT book he saw number 6 **I feel down.**

Number 6 in the feelings chart was about sadness.

John put the number 6 in his diary and thought I must look at the coping part of the SAINT book to see if I can help myself.

There John saw ideas that could help him.

WEEKLY DIARY	
Monday	**Friday**
6 **16**	
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**



I know, "I will listen to music" this was number 16 **listening to music or TV**
John then put number 16 in his diary

John also wrote a note in his diary that this made him happy

EXAMPLE 2

WEEKLY DIARY	
Monday	**Friday**
6, 7 **11**	
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

Charlie was feeling angry and upset and she did not want to look at her SAINT book.

Charlie was approached by staff who asked was there anything that could be done to help.

Charlie shouted "no one listened to her". The staff said that they would be happy to talk to her as long as they could talk calmly together.

After talking Charlie felt much better. The staff praised Charlie for how well she had been able to calm down

Later in the day Charlie asked the staff to help her put about her day in her SAINT book

Together they looked at the SAINT book and described how Charlie had felt.
Charlie had felt upset **6. I feel down today** and angry **7. I don't feel in control**

Charlie put the numbers 6 and 7 in her diary
Charlie had done well to stop being angry by talking to someone in her team **11. Talking about it.** Charlie then put number 11 in her diary, and then wrote a note in her diary that this had worked

EXAMPLE 3

Leroy had just had a day out with staff to the seaside.

This had made him happy.

Before he went to bed he remembered to look at his SAINT book.

Thinking about his day, Leroy felt he had felt good all day.

Leroy wanted to put this in his SAINT book.

Leroy went to the Diary and put OK

WEEKLY DIARY	
Monday	**Friday**
OK	
Tuesday	**Saturday**
Wednesday	**Sunday**
Thursday	**NOTES**

EXAMPLE 4

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
Wednesday **4** **12**	**Sunday**
Thursday	**NOTES**

Jesoda was finding it hard to do things, so she looked at her SAINT book.

Jesoda was not a good reader, so she asked a friend she knew well to help her.

Together they looked at the SAINT book and her friend explained to her what was in the SAINT book.

Jesoda said number **4. I find it difficult to do things** was how she felt

Jesoda put the number 4 in her diary after her friend had shown her

Her friend said we should look at the coping part of the SAINT book to see if there is something we can do to help.

There Jesoda's friend told her about the ideas of how she could help herself.

Jesoda chose remembering how well she had done in the past this was in **number 12 positive thoughts.**
Jesoda then put number 12 in her diary. Jesoda's friend then wrote a note in her diary for her to say that this had worked

EXAMPLE 5

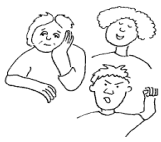
Ben had felt miserable all day, spending his time alone.

When people asked him to do his SAINT book he said later

Ben had forgot what he said and went to bed to sleep

The next morning Ben felt a bit brighter and staff asked him if he wanted to talk about yesterday.

Ben said yes and bought his SAINT book to help him explain how he felt. Even with the SAINT book Ben found it hard to describe because he did not feel sad and miserable



The staff said **no 9 I feel emotional** can be used when you feel like that.
Ben then put number 9 in his diary.

Because Ben had not used the coping strategies he did not have to put a number in the diary from this part of the SAINT book.

Ben did write in his diary to say he felt better

WEEKLY DIARY	
Monday	**Friday**
Tuesday	**Saturday**
	9
Wednesday	**Sunday**
Thursday	**NOTES**

7.14 **Appendix 6 Interview transcripts Participant 7 interview**

Have you used your book? *I have used it yes*

How was it? *I have found it very good and found it very helpful a lot of people have written down feeling diaries sad and helpless sought of thing and has helped me with my moods as well. I write down how I an feeling it is a feeling book that helps me with my moods it has given me the chance to think about my feelings am I depressed as well as positive stuff. As well as negative stuff you have to think about the positive stuff because this year has been up and down for me, its been terrible to start with but now it is getting better slowly. And I am very proud because there are things like moving, new job and new prospects are coming up for me.*

Is there anything you liked about the book itself (design or layout?)*Front cover it looks like a woman and a man and reminds me of me and my wife and people together and it is a very good how it is laid out I can't read it but it looks understandable. I like the pictures; I am pleased it has pictures in. People with learning disabilities, help them to understand more rather than joined up writing.*

Have staff found the SAINT easy to use? Have they supported you? *They have yeh. Written things down in the book.*

Have the staff been able to support you? *I haven't been able to write things in the last couple of times staff have been busy doing things with other people, but I do use it when I can.*

You have told me before about looking at the pictures can you tell me more about that? *Yes*

Can you tell what they mean? *If someone has a sad face or is laughing they have a happy face or like miserable depressed unhappy. I recognize by the pictures and it has been helpful.*

Would you like to see different versions poster less pictures? *I'll tell you the truth, more pictures for people like myself who cannot read for those that can read more writing and things sort of thing cause some people with learning disabilities can read, we all have different things. A guy I know is a good reader so pictures would not be so good for him. I also know guys like Ian who needs pictures like the people in my house. The pictures are also good for people learning to read and pick up words.*

Perhaps photos rather than pictures? *Not sure. I suppose so but if it is confidential not sure if it could go to the outside world just the office.*

I meant picture in the book for example a person being sad *Oh yeh.*

Or pictures talking to someone so it is more like a book? *I quite like the pictures but not on refrigerators where everyone can see them. I knew a girl with a mild learning disability where they stuck her stickers on the wall where everyone could see, see said that made her feel babyish. When she went out to college people would ask her questions and she would get a bit embarrassed like. Pictures in the book are ok but not put up in supported houses. If you go in my house there are picture on the wall. Now I am moving I have asked Dionne if she feels this is all childish. The other guys feel it is childish, she said oh this is the rules of the house.*

So would you like to see different books for different people? *Yes I was telling you about the Guy we all have different needs?*

Bigger books with large print? *Like brail for blind people, one guy who used to be in my house could not see but he could feel it so he would feel and know it was - E. It is like me I know the letters P-A id that PA? Yes, P-A-C- K- S- A- I- N- T I know the letters but cant put it all together.*

Can you recognize some things? *Newspapers The Sun I know S for sale.*

Did you use the book at any particular time of day? *I just used the book any time I get depressed, sometimes I use it during the day if I got staff I can talk to. Some staff can be sought of thing, not very understanding and if I get a reasonable staff there like my keyworker James and Rainer. I know I can say to them. There was one morning I know I shouldn't have done it, they was rushing to get all the guys to the classes. "They have got to get to classes, they have got to get to classes, they have got to get to classes" I was told. I was feeling a bit depressed and left out so I got my book out. I said to Rainer would you help me with my book. I did ask the night before so there was no excuse, they kept saying tomorrow in their own words, s Rainer is a lovely lady, sorry I do apologize and she said I wish you had asked me last night P***, well Rainor I did actually ask a couple of staff here last night. She said because the evenings are better they say that the always the next day. She said she would write something in it when the mini cab come so my keyworker said we would do it outside but he didn't do it either, I thought this is charming he said don't worry P*** we will do it tonight but he did not do it. I need this so I can talk to Eddie*

about my depression so I felt a little bit let down it was not my key workers thought and I od get to do it the next day.

Do you think it has actually helped you? *It has helped me sometimes when I have a good cry I can look at it and say I was depressed or other reasons I can say I had a bad day. The next time I cold put I has a good day, a nice and happy day I can also put about me job, moving so good on one page bad on another.*

Have you looked at the coping strategies? *Yes sometimes it is not easy to talk to staff all they will say to me some won't answer some will tell ne to sit down or what's the reason because there so bust looking after the other service users and they look at me because I am an independent man but that's rubbish because any one can get depressed so what I d is I use this book. So if no one is here to help me I will look at these pictures then I try to remember the words of my mother to help me Positive thoughts, yes positive thoughts I try to remember the words of my wife to help me and other people telling me not to worry and the smiling faces cheer me up and all that depression sort of lifts.*

What about hobbies? *Yes I think about my holiday, seeing people I like, going to the pub. People chatting socializing not just going to learning disability clubs but out to mainstream. I was quite shocked the social worker is moving me out of the house and I will miss these guys it an achievement in one way I wont have the staff around me giving me the cold shoulder, it is better for me to move to outreach and be independent.*

Anything could be taken out or think what is that for? (shows book,) *Relaxation, exercise, sleeping mixing with people helps me.*

Is there anything to change? Or do you have anything else to say *A very good book a very helpful book I really liked it.*

7.14.1

Participant 2 Interview

Have you used your book? *Yes*

Did you read it? *Yes*

Did you like it? *Yes*

What did you like? *I liked it*

What did you like? *Forgo*

7.14.2

Participant 4 Interview

ED was with another participant (no 3 KD) both chose to do this.

Have you used it at all? *No*

Have you used it with me useful? *Yes*

Anything you like? *It looks all right, I like the pictures*

What about the diary? *I like the pictures*

Anything you do not like? *I don't know.*

How would you describe it ? *Sometimes hard to understand.*

Any way it could be better? *I would like photo.s*

Is it easy to say you feel upset? *I feel ok*

What about posters instead of books? *No.*

7.14.3

Participant 14 Interview XC declined to be interviewed

Participant 8 Interview

Did you like it? *It was OK.*

What good things? *It was all right it was interesting.*

Have you ever written in the book? Yes interesting. *I did it on my own. What I do each week, just good things. Would write about being worried.*

Why? *Forgot.*

123 Could you think of ideas to make the SAINT better? *No*.

124 Did you use the cooping strategies? *Not sure did when prompted.*

125 **7.14.4**

126

127 **Participant 1 Interview**

128 Did you use it? *Forgot about it*

129 Are our meetings useful? *Yes I like meeting others*

130 Do you feel coping strategies or useful? *I like the book it is alright.*

131 Is it easy or difficult? *It was easy.*

132 What did you like would you change it? *No*

133 **7.14.5**

134

135 **Participant 3 Interview**

136 Have you used the book? *No.*

137 With me? (researcher) *Yes.*

138 What do you like? *The pictures.*

139 Have you asked the staff to help? *No they are too busy.*

Have staff approached you? *No.*

What about the coping strategies and feelings? *I like the coping strategies.*

Anything you do not like? *Writing to small I am good at reading. I don't get the feelings. The questions are a bit hard to understand. Print could be bigger. Pictures with different writing. Different books for different people big one and small one. I would like photos.*

7.14.6

Participant 5 Interview

Did you like it? *Good things.*

What good things? *It was nice.*

Have you ever written in the book? *Never.*

Why? *Forgot.*

Did staff help you? *Staff helped me some weeks a little.*

Did you enjoy it? *Yes.*

Is it easy or difficult? *Difficult.*

7.14.7

Participant 6 Interview

Are our meetings helpful? *Yes.*

Do you feel the coping strategies are helpful? *Yes it said things that help.*

Was it easy or difficult? *It was easy.*

What did you like? *It helped me say how I was feeling?*

What would you change? *Nothing.*

Have you used your book? *Not this week.*

But before this week? *Yes.*

Did the staff help you with the book? *Some staff did.*

How would describe the book? *It's a feelings book.*

How have you found the book useful? *Easy to tell someone if you're upset.*

It helped me.

Participant 10 Interview

Interview: Not completed

7.14.8

Participant 15 Interview

How have you been since I last saw you? *OK.*

Have you used the SAINT? *Yes it was good.*

Were there things you particularly liked about the SAINT? *Good I liked the pictures and the flow.*

Were their things you did not like about the SAINT? *N.o*

If you used it how did you use it and was it at any particular time of the day? *Anytime.*

Could you tell me how you filled it in; did other people help? *I filled it in my Mum helped me*

Is there anything that you feel would make it better? *Photos rather than pictures. A place to put about gym and church (weekly planner for routine)*

Is there anything you do not like in the SAINT that you would change? *Put more things in it what I am doing.*

Is there anything else you would like to tell me? Can you write to me and my Mum to give me the graph and say how I done.

Participant 11 Interview Declined

Participant 12 Interview

How have you been since I last saw you? OK

Have you used the SAINT? *I read the book while doing my homework. I would read but not write in it the second time, which was as helpful*

Were there things you particularly liked about the SAINT?.....(if yes) Could you tell me more? *How to cope with stress, how to stop worrying*

Were their things you did not like about the SAINT? *No things I did not like*

How did you use it and was it at any particular time of the day? *Whenever I picked it up*

Could you tell me how you filled it in; did other people help? *Did it on my own I found it very easy.*

Is there anything that you feel would make it better? *More things to read especially good things about being well..*

Are there any parts you feel should be taken out? *No.*

Is there anything you do not like in the SAINT that you would change?

No.

Is there anything else you would like to tell me? *No.*

7.15 **Appendix 7 SAINT User Presentation**

WELCOME
TO
THE
SAINT Part I

The SAINT

The SAINT is about how you cope with low moods, stress, frustration and other emotions.

If you're Sad 

If you're Confused 

If you're Angry 

Always find ways to manage problems which may make you feel stressed, frustrated, upset and worried and be chilled out.

The SAINT has helped me a great deal to alter my emotions. There are two sides of a story, the Bad/Ugly and the good side by Phil Collins.

The most important thing to do is, always think about the best way you cope with stress.

The SAINT is a Diary to help with thinking through how you cope with life, the good ways and the bad ways.

Point A → started being angry

Think about coping strategies → Try to stay calm

Think about coping strategies → Calm down and relax

Always take the correct steps toward controlling your anger on a regular basis.

The Diary

Each day of the week you can fill it in.

Monday	Friday
Tuesday	Saturday
Wednesday	Sunday
Thursday	NOTES

This is a daily diary of what is happening. Good day, Horrible day, Bad day, or Boring day.

Coping Strategies Chart

There is a Chart to think about the best way you cope with things. There are lots of ways of coping when you are angry or stressed. For me, getting out and away from people keeps things under control.

Talk about it

Think Positive Thoughts

Coping Strategies

Go for a walk

Relax!

Coping Strategies

Spend time with friends

Write in your diary

Monday	Tuesday

Coping Strategies

Watch TV

Keep Busy with something you enjoy

The SAINT

The SAINT can help with knowing when you are getting angry and frustrated.

Frustration - red faces

Confused

Showing hands

It is good to know the signs. I know the problems have already started when the face gets red.

Welcome
to
the
SAINT 2

This is a cloud of tears showing low and unhappy

The SAINT

The SAINT tells people what it means etc etc. The SAINT covers all the negative feelings and makes you think about the best ways of how you cope. We all cope in different ways. That's the good thing about SAINT, it's personal, it's only about you and what's the best for you!!

Sad

Thought

Happy Again

I like doing the SAINT because its

Wacky!

Fun!

Cool!

Hard Working!

The SAINT from The Dell!

The saint is a famous name due to a football team called Southampton F.C which basically is a football team on the South Coast.

The Dell

The famous ground called the DELL - Come on Saints!! That's where the name called the Saints came from.

I like doing SAINT

I am the famous SAINT person

Is guided self-help a treatment option for people with intellectual disability?

Accompanying Compact Disc: Weekly Data and Visual Analysis

Eddie Chaplin

Health Services and Populations Research Department

Institute of Psychiatry

King's College

University of London

Doctor of Philosophy (PhD) Thesis

March 2013

INTRODUCTION

This following compact disc contains the raw data from the Service User and Clinical expert consultation along with data and visual analysis for all SAINT participants, in parts 1 and 2 of the study.

Visual Analysis for part 1 contains the data for all 15 participants. Data is presented by participant and consists of weekly scores and visual analysis (i.e., The mean, trend, variability, overlap, immediacy, and consistency) for the SAINT, Glasgow Depression Scale-Learning Disabilities and Glasgow Anxiety Scale-Intellectual Disabilities.

Visual Analysis for part 2 contains the data for all 3 participants. Data is presented by participant and consists of weekly scores and visual analysis (i.e., The mean, trend, variability, overlap, immediacy, and consistency) for the SAINT, Glasgow Depression Scale-Learning Disabilities and Glasgow Anxiety Scale-Intellectual Disabilities.

Visual analysis comparing the mean and median are presented in the main thesis

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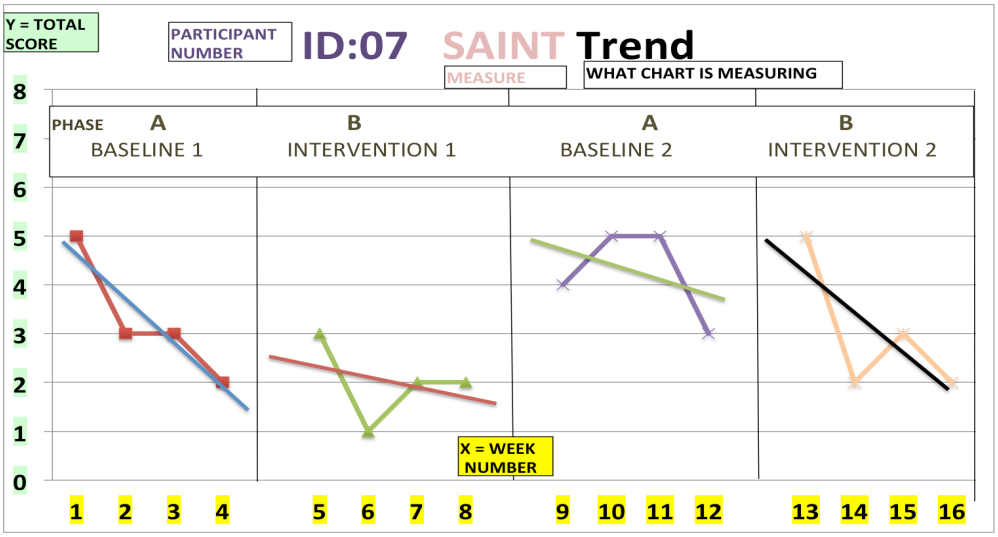
SINGLE CASE RAW DATA GUIDE TO CHARTS AND TABLES

This process examines both within and between data patterns in order to establish if there is a causal relationship (1) level, (2) trend, (3) variability, (4) overlap, (5) immediacy of the effect, and (6) consistency of data patterns across similar phases. Duration of the phases for parts 1 and 2 of the study are given below.

Part 1	**Part 2**
Baseline 1 (A) weeks 1-4	Baseline 1 (A) weeks 1-7
Intervention 1 (B) Weeks 5 -8	Intervention 1 (B) Weeks 8 - 12
Baseline 2 (A) Weeks 9-12	Baseline 2 (A) Weeks 13-17
Intervention 2 (B) Weeks 13-16	Intervention 2 (B) Weeks 18-22

The illustration below is a guide to aid understanding and to interpret the SCED charts that follow. The y-axis denotes score on the stated measure whilst the X-axis is the number of weeks the intervention took place.



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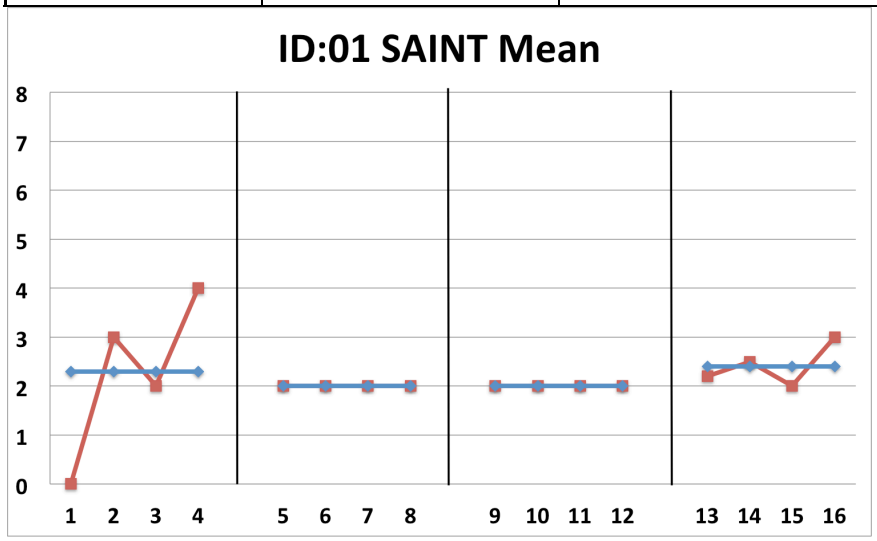
In the participant weekly scores that follow bolded figures are used to indicate a mean score where sessions were missed.

PART 1 SCED

ID-1 WEEKLY SCORES AND VISUAL ANALYSIS

Week	SAINT	GDS-LD	GAS-ID
1	0	1	1
2	3	6	2
3	2	7	3
4	4	8	5
5	2	3	3
6	**2**	**3.7**	**2.3**
7	2	4	4
8	2	4	0
9	**2**	**5.5**	**3**
10	**2**	**5.5**	**3**
11	2	7	4
12	2	4	2
13	**2.2**	**5**	**3**
14	**2.5**	**5**	**3**

15	2	3	1
16	3	7	5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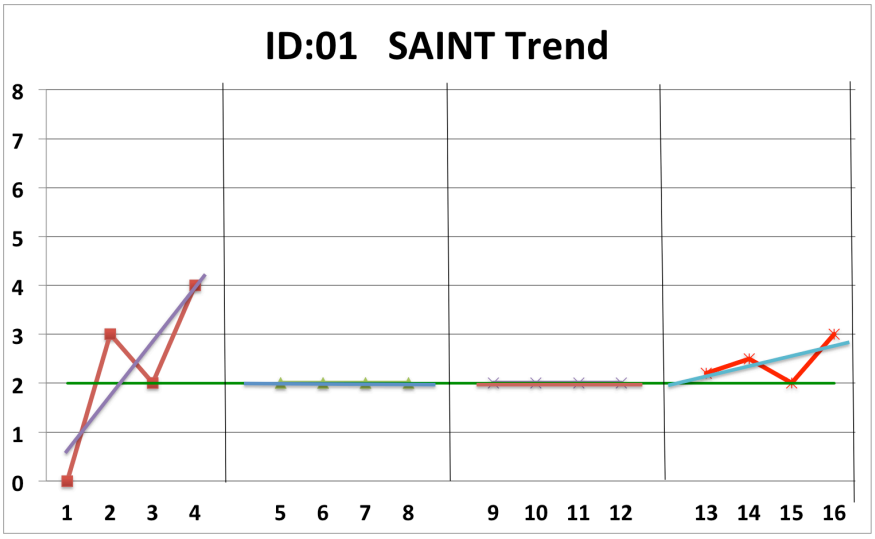
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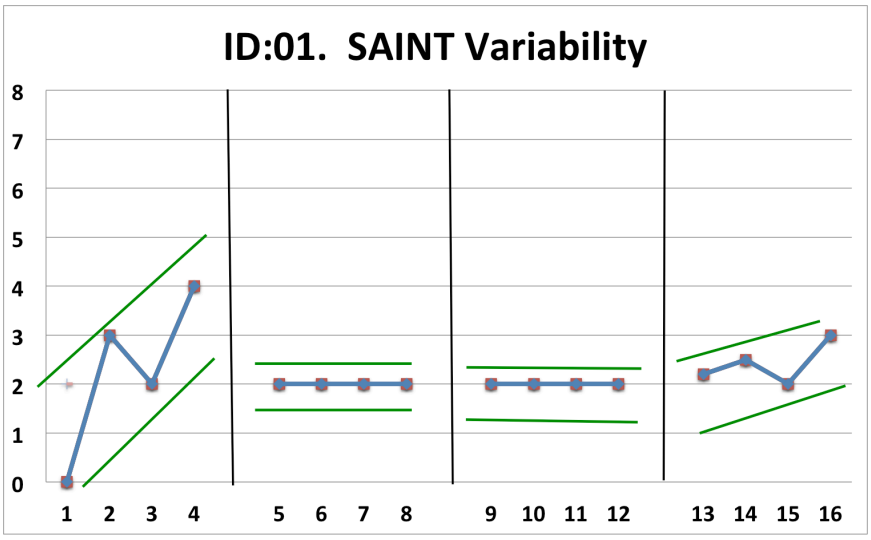
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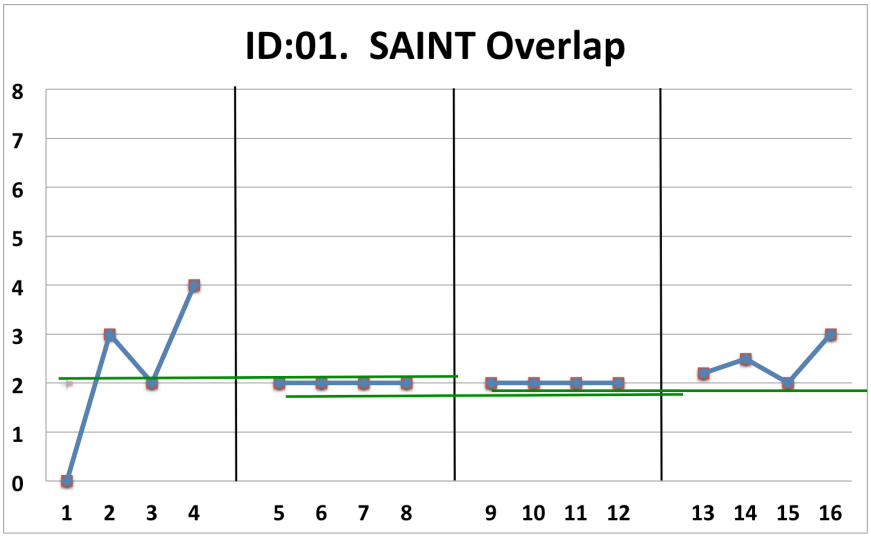
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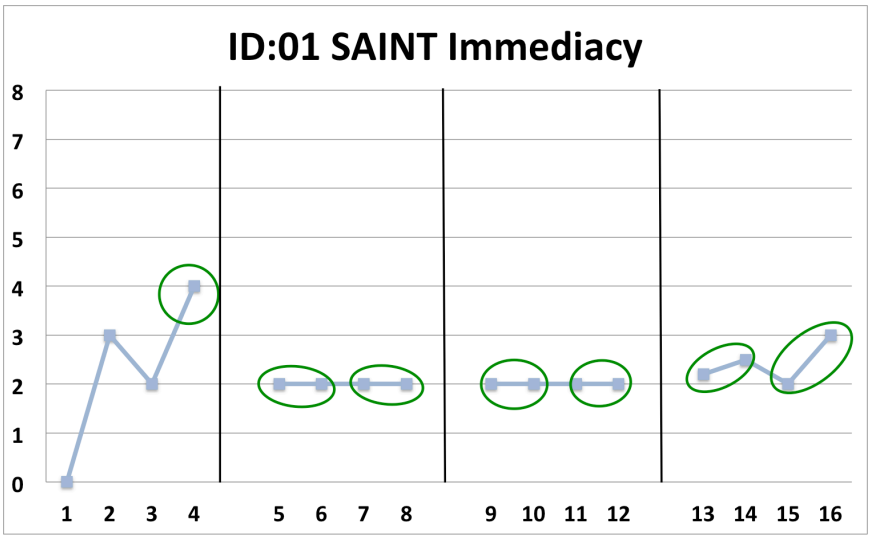
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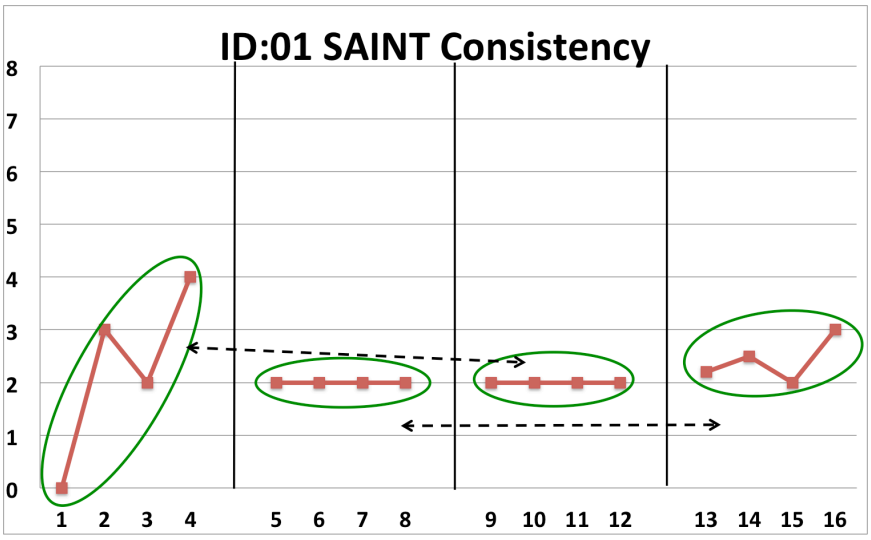
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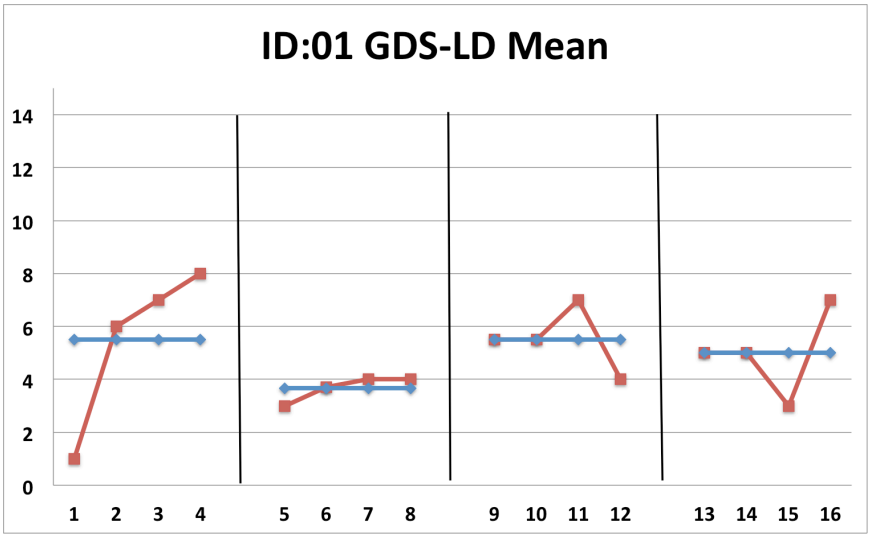
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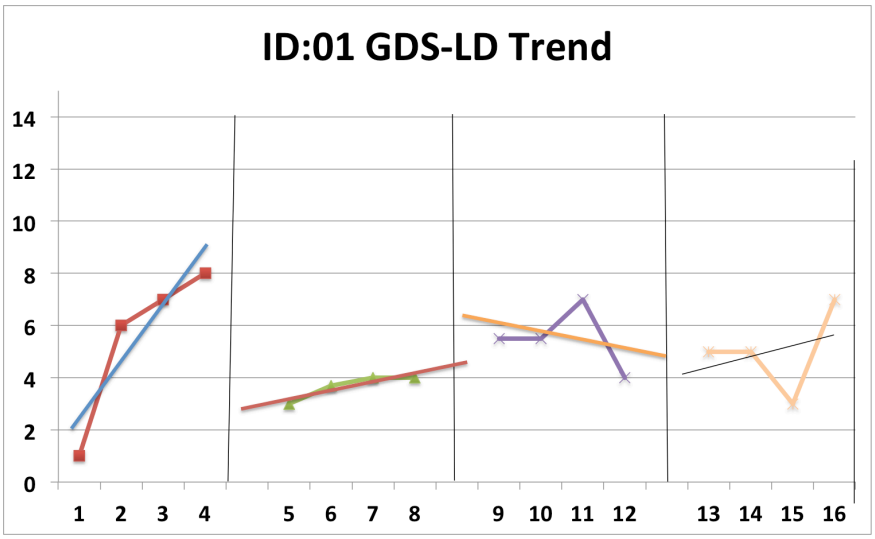
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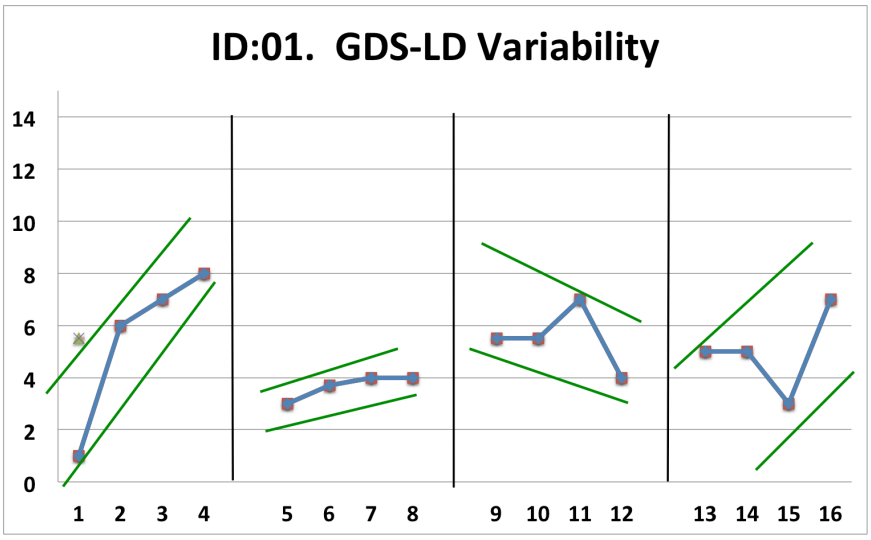
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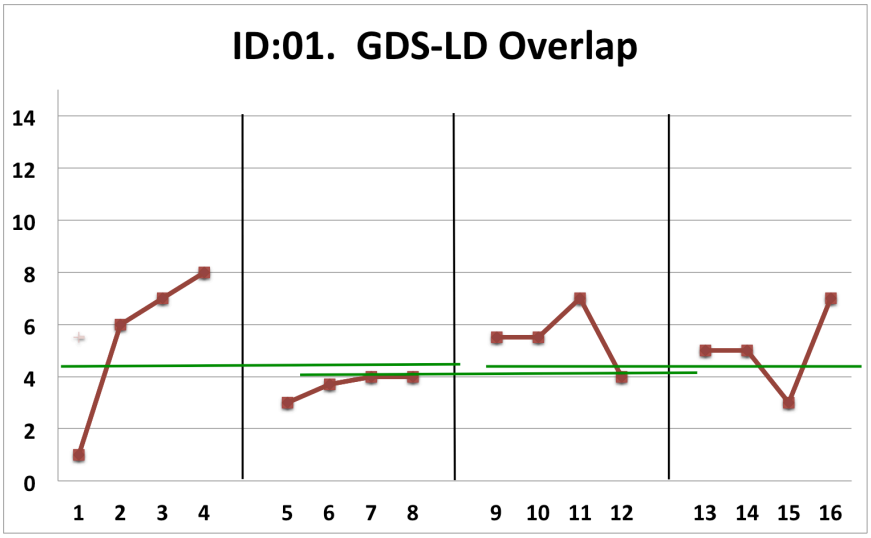
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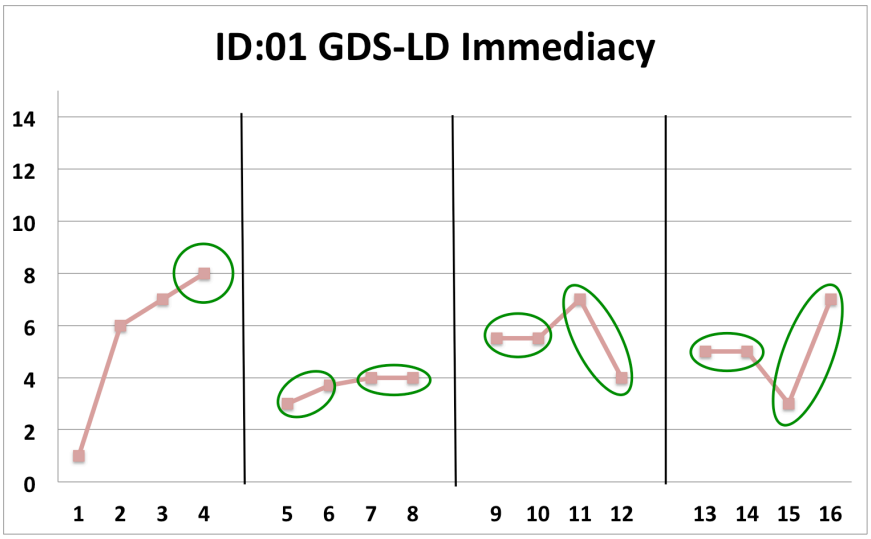
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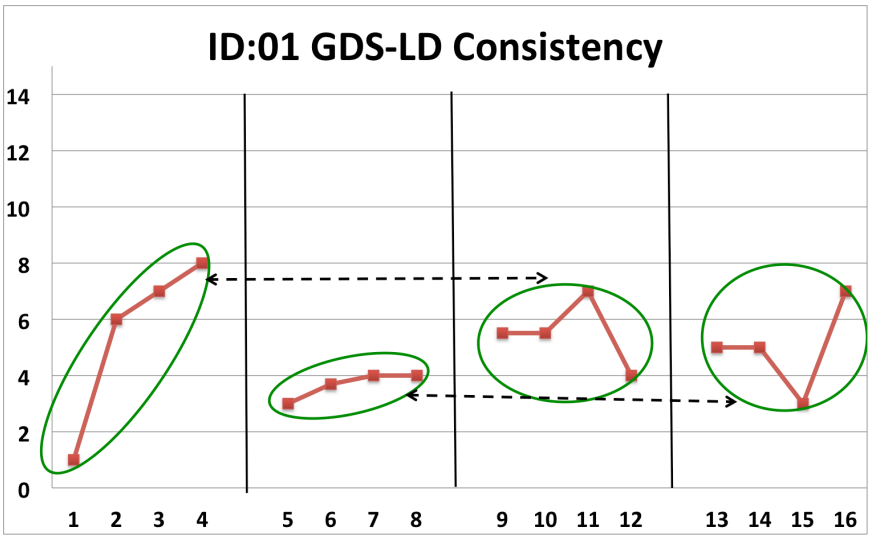
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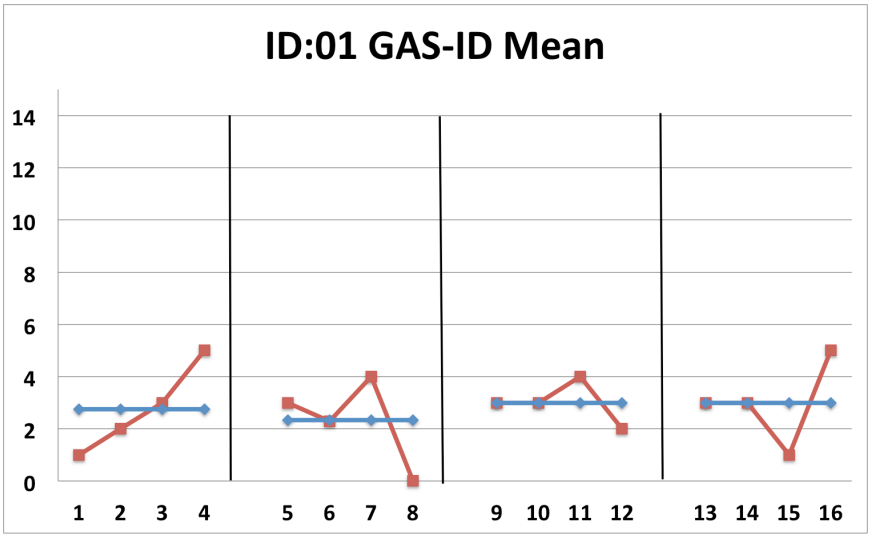
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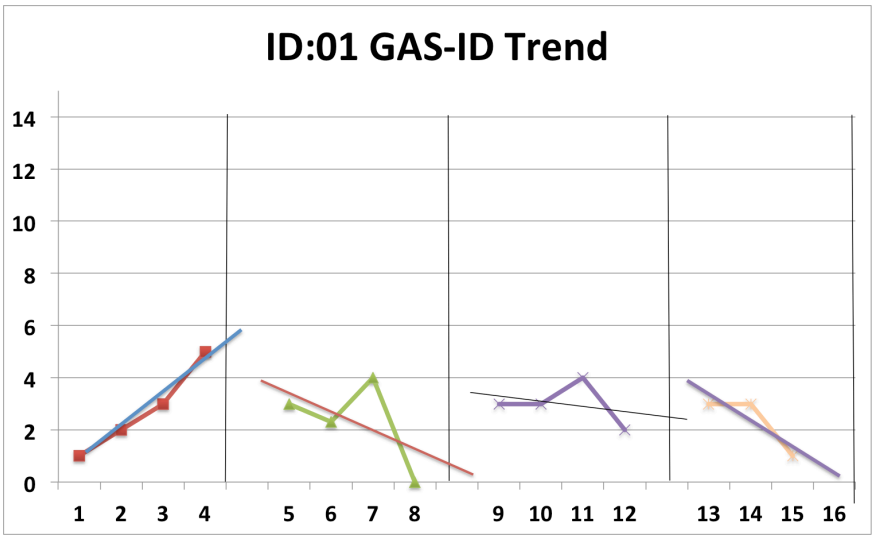
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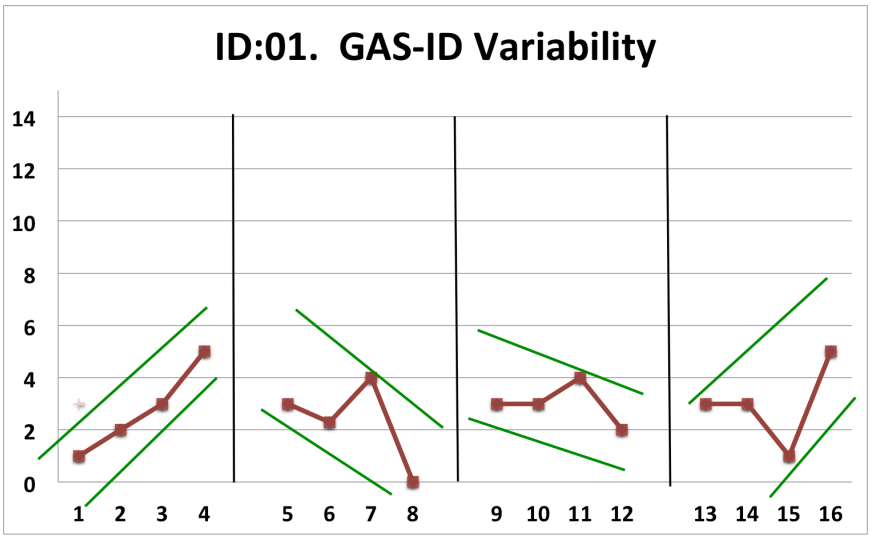
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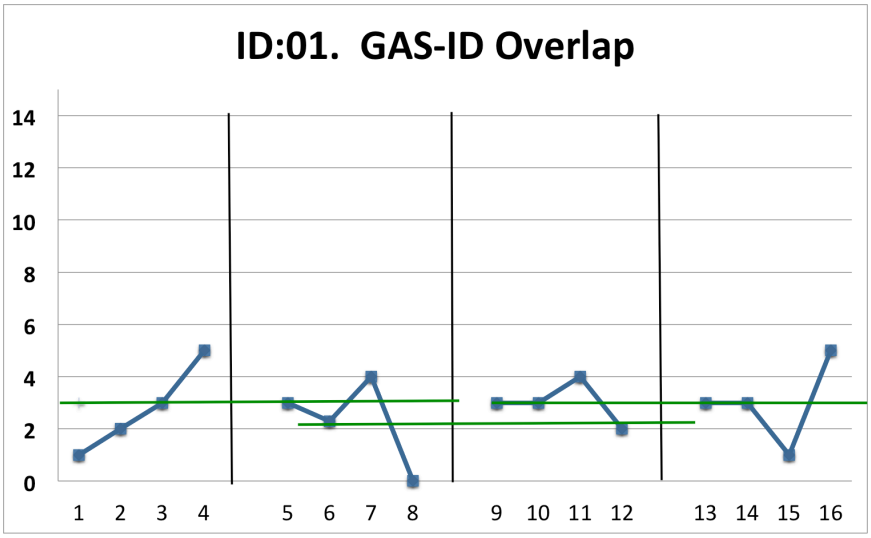
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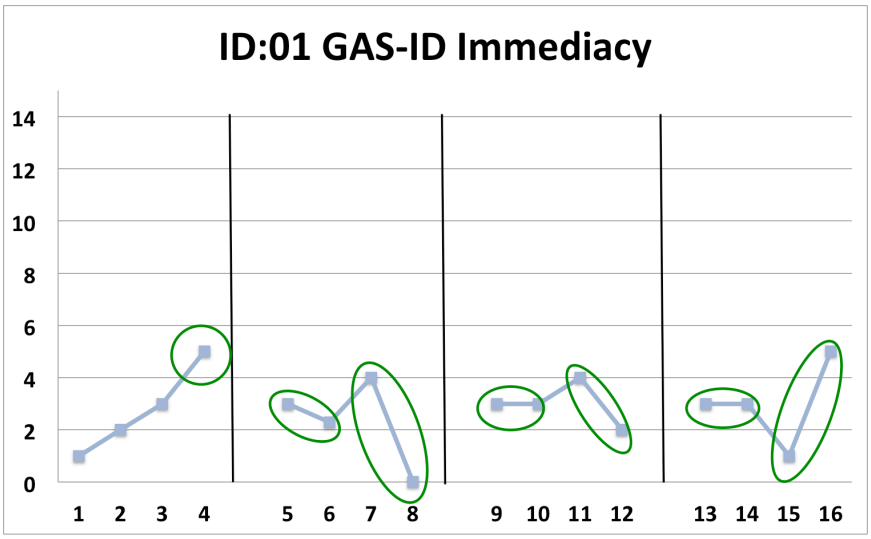
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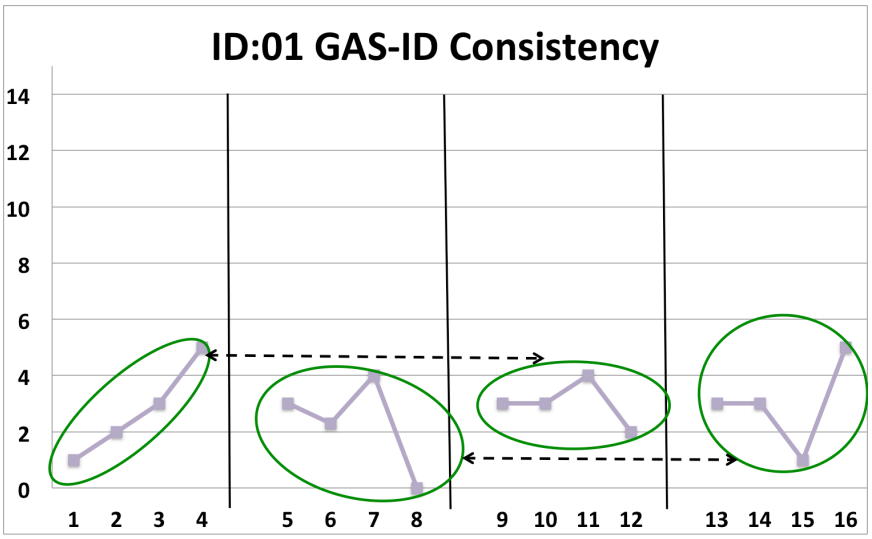
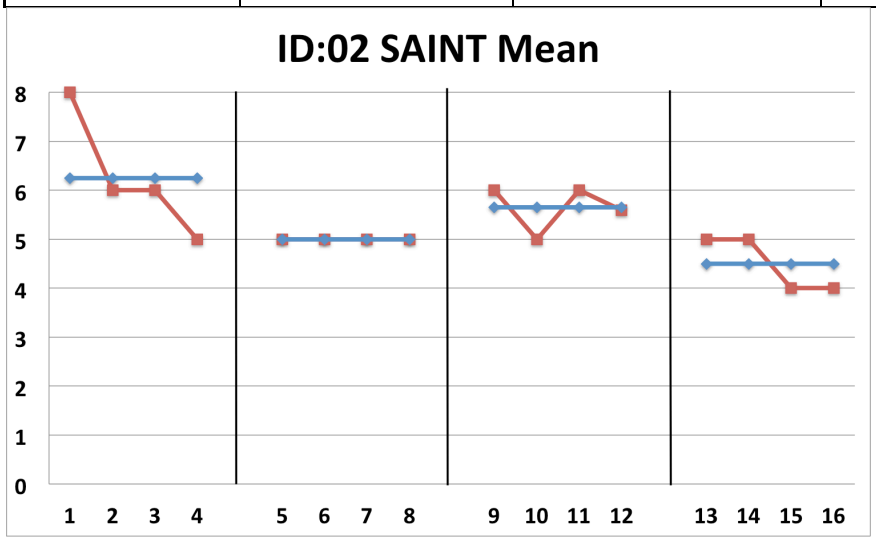
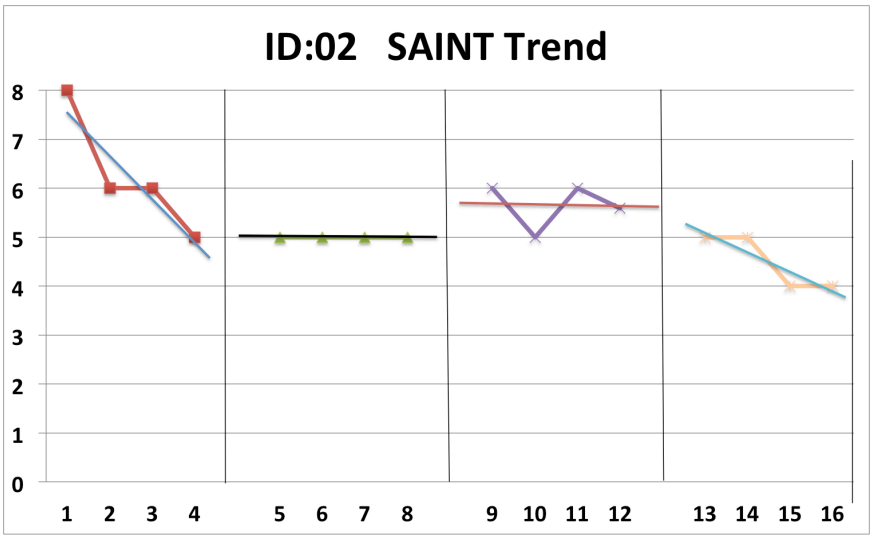


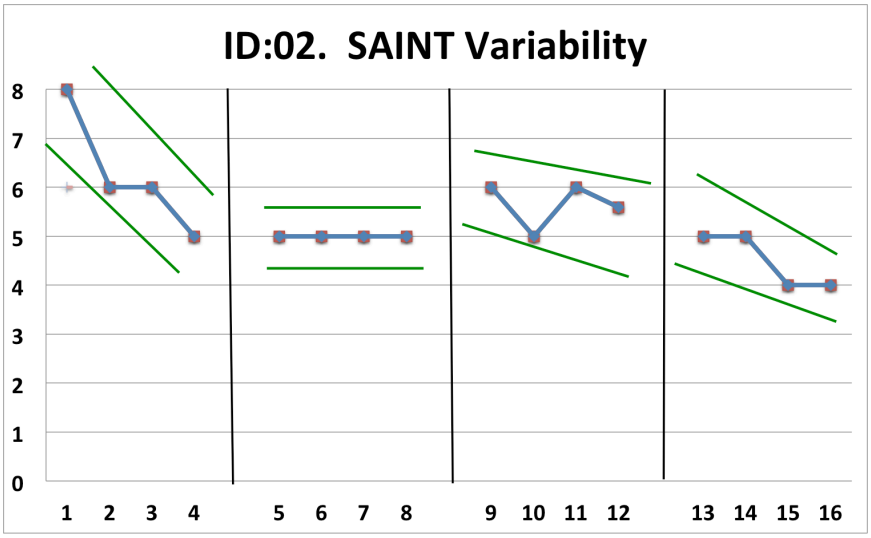
ID-2 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	8	14	7
2	6	17	9
3	6	14	15
4	5	10	9
5	5	9	11
6	**5**	**10.3**	**10.3**
7	5	12	10
8	5	10	10
9	6	10	12

10	5	10	11
11	6	12	10
12	**5.6**	**10.7**	**11**
13	5	11	11
14	5	7	9
15	4	8	9
16	4	7	5




ID:02 SAINT Trend
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02. SAINT Variability
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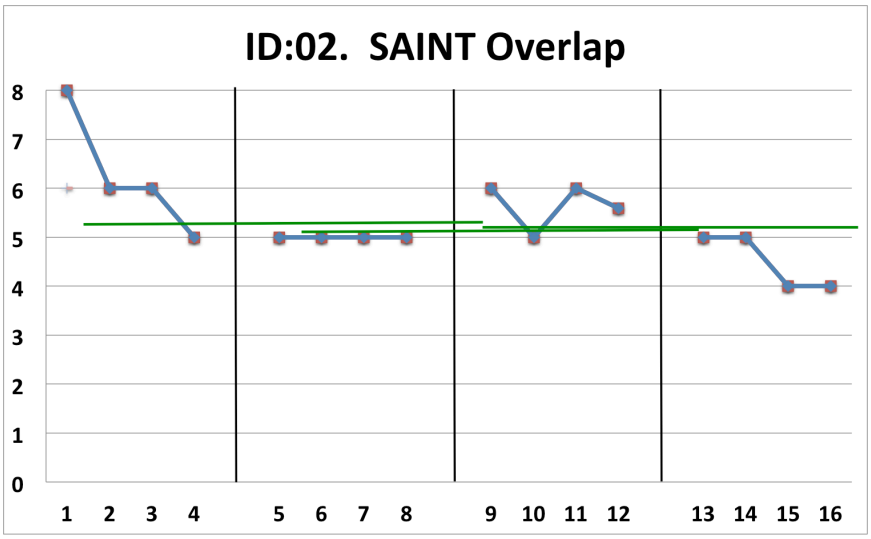
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02. SAINT Overlap
8
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4
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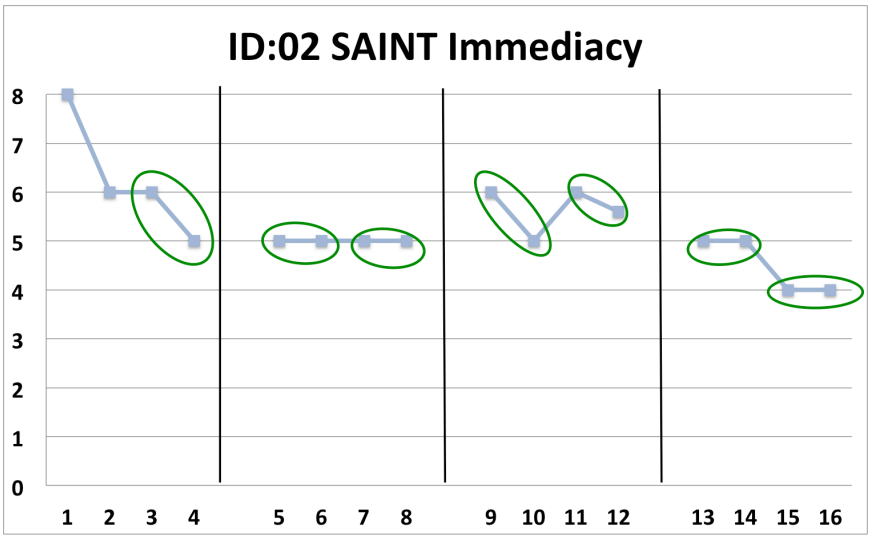
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02 SAINT Immediacy
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1
0
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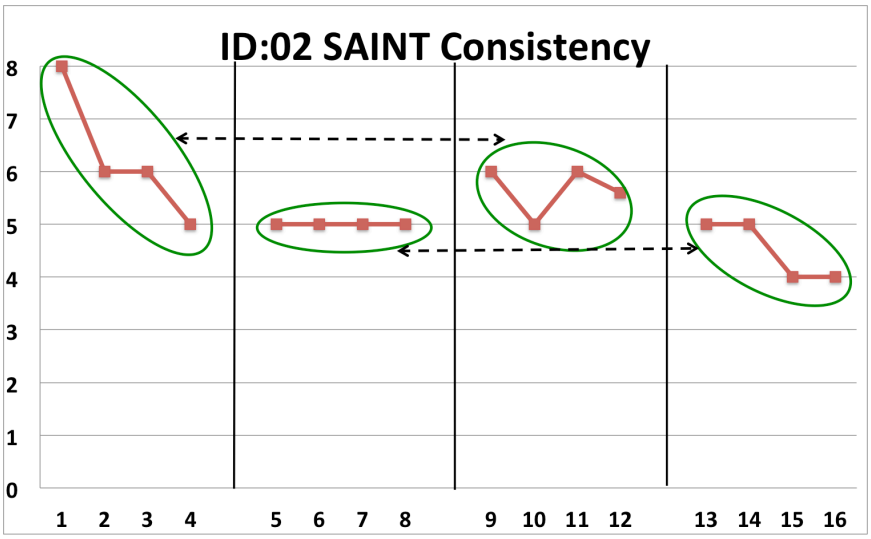
ID:02 SAINT Consistency
8
7
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5
4
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1
0
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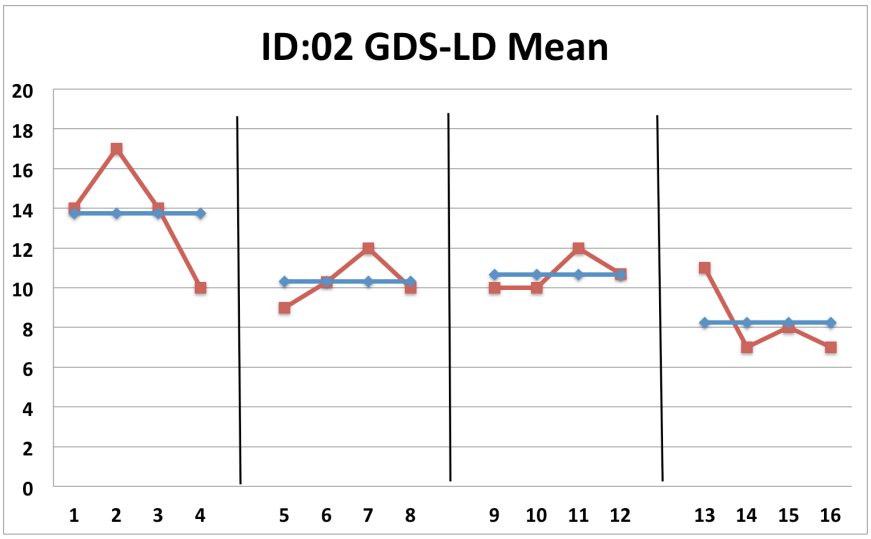
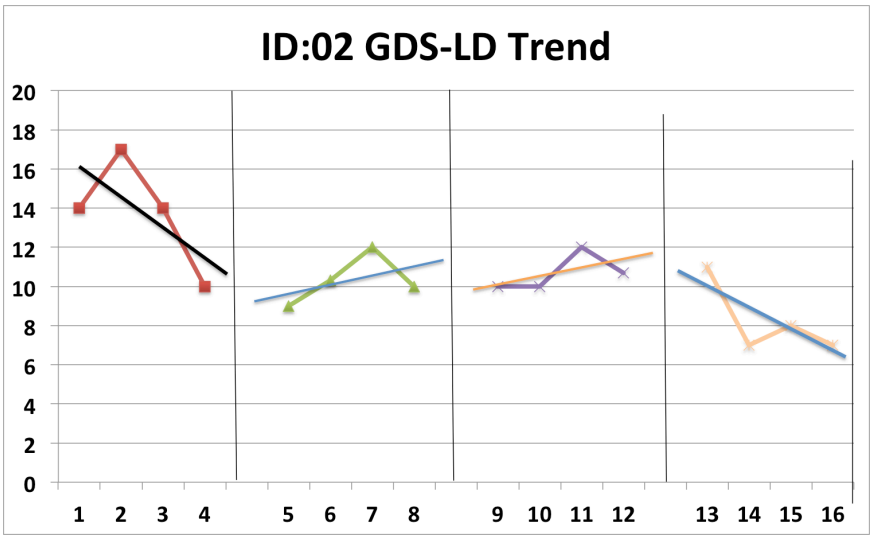

ID:02 GDS-LD Mean
20
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02 GDS-LD Trend
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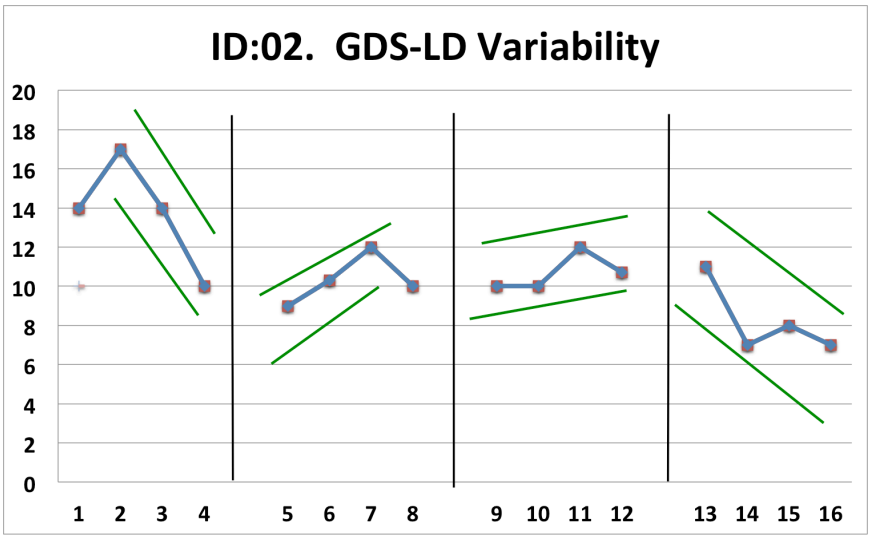
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02. GDS-LD Variability
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18
16
14
12
10
8
6
4
2
0
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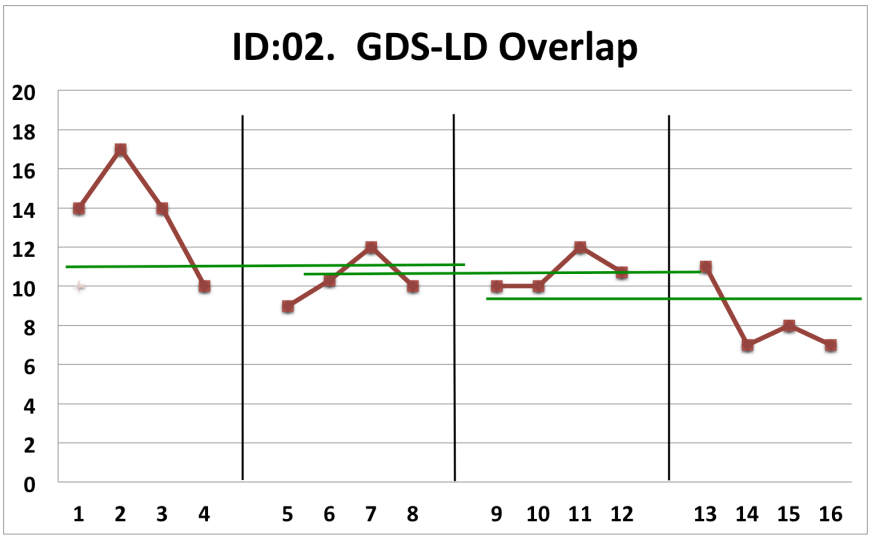
ID:02. GDS-LD Overlap
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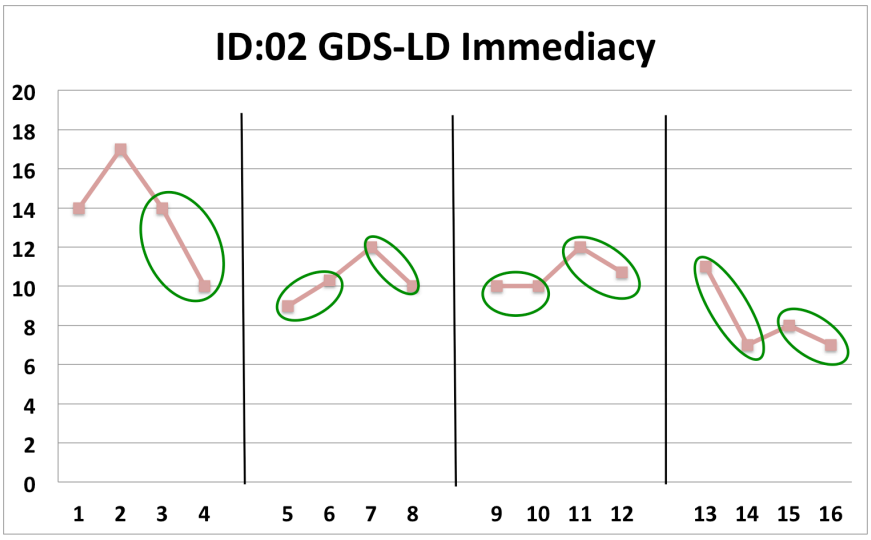
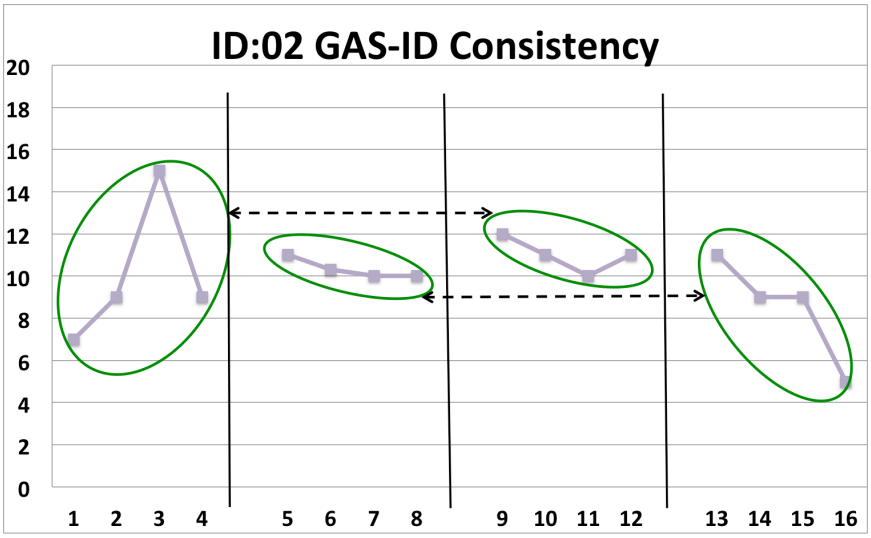
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02 GDS-LD Immediacy
20
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02 GAS-ID Consistency
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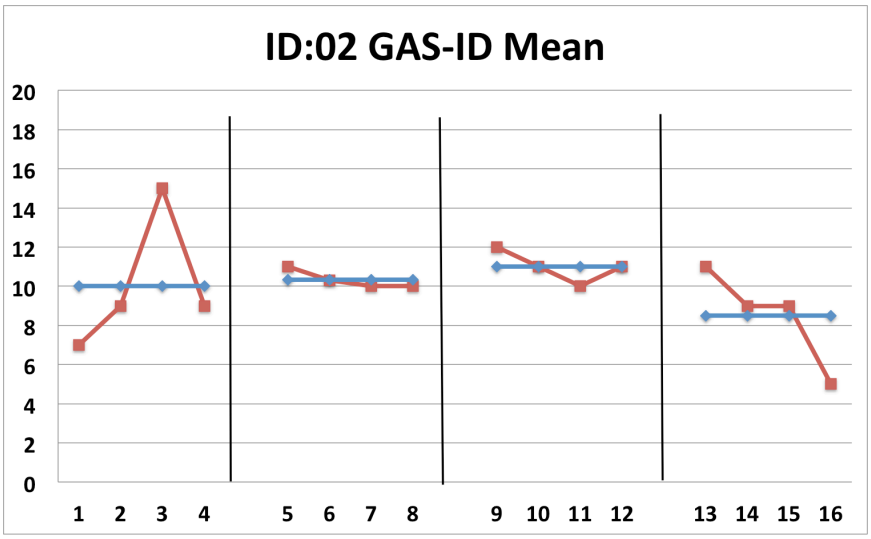
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02 GAS-ID Mean
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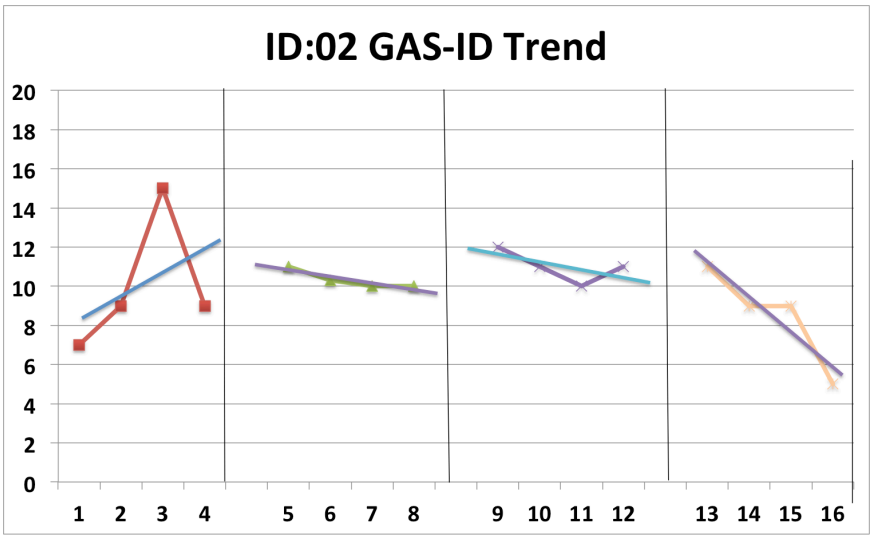
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02 GAS-ID Trend
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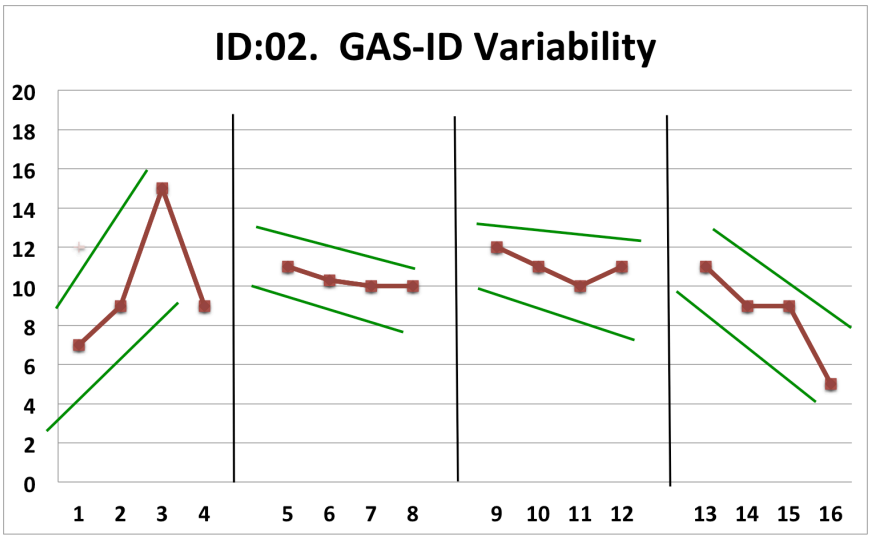
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02. GAS-ID Variability
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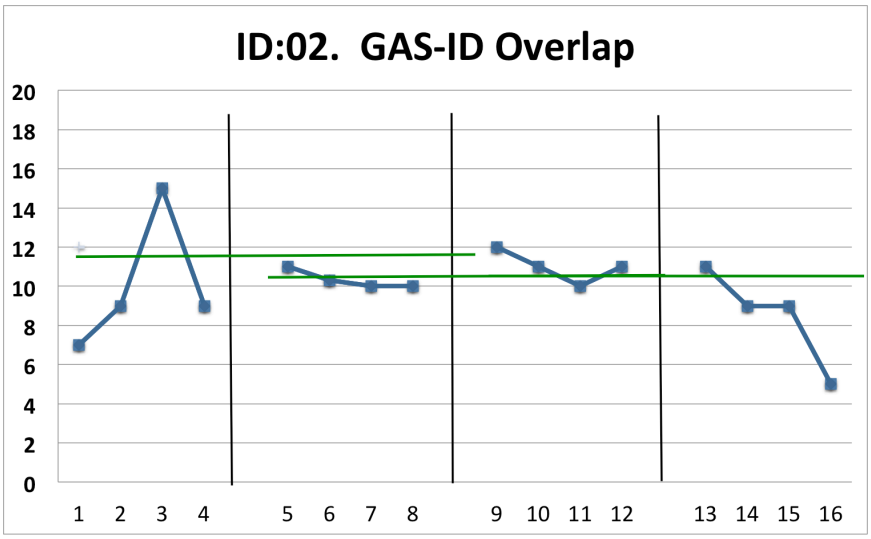
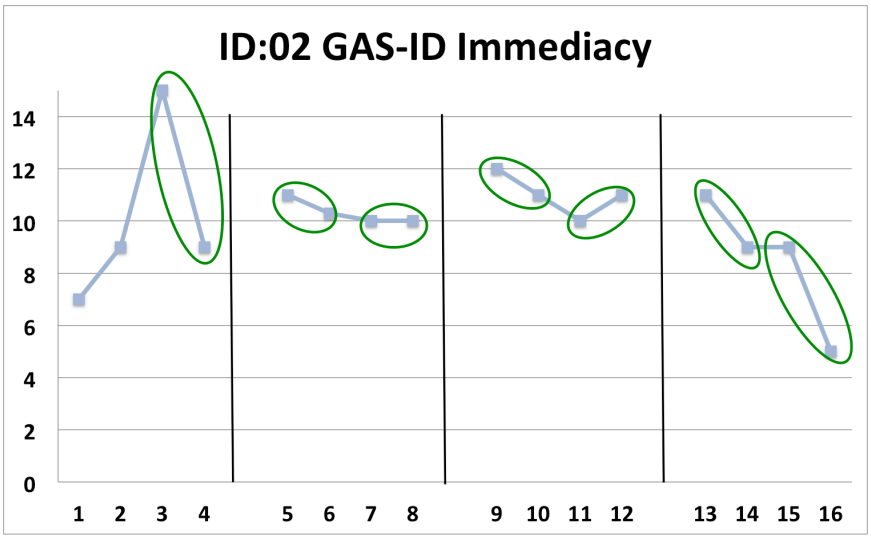
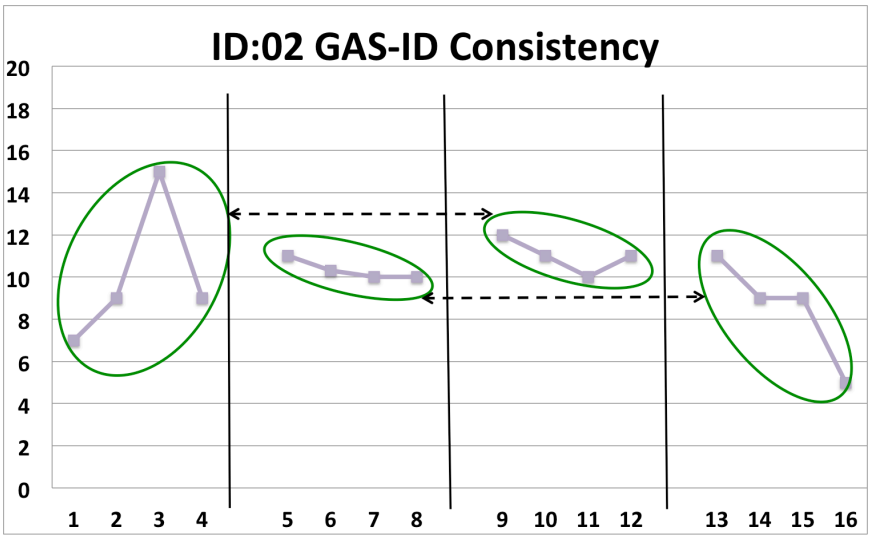
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:02. GAS-ID Overlap
20
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

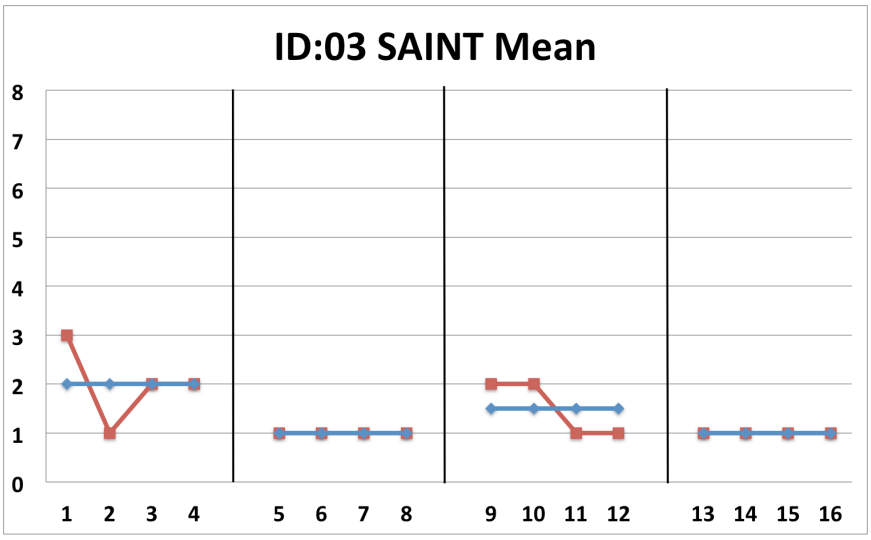


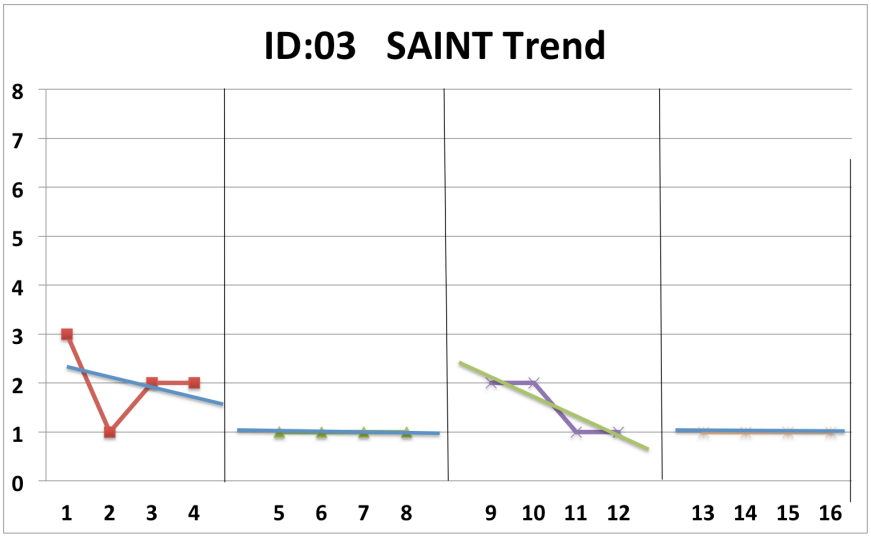


ID-3 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	1	3	4
2	2	2	2
3	0	2	0

4	2	3	1
5	1	3	1
6	**0.7**	**2**	**1.7**
7	1	3	3
8	0	0	1
9	1	1	2
10	0	0	1
11	0	0	1
12	1	2	1
13	0	0	1
14	0	0	1
15	**0**	**0.3**	**0.7**
16	0	1	0


ID:03 SAINT Mean
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03 SAINT Trend
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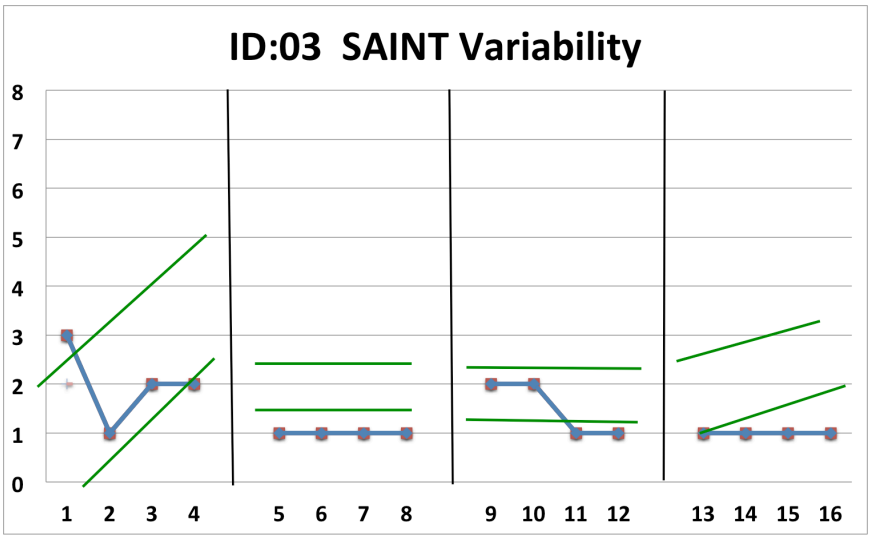
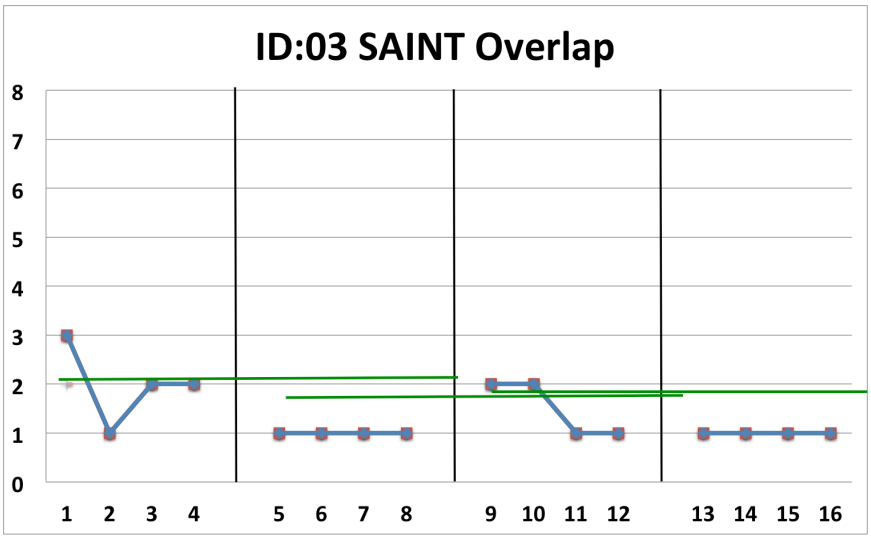
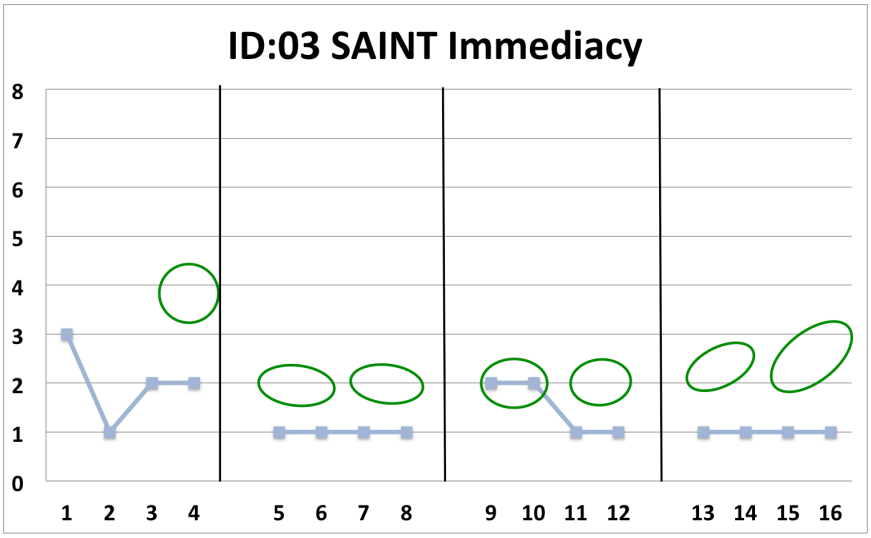
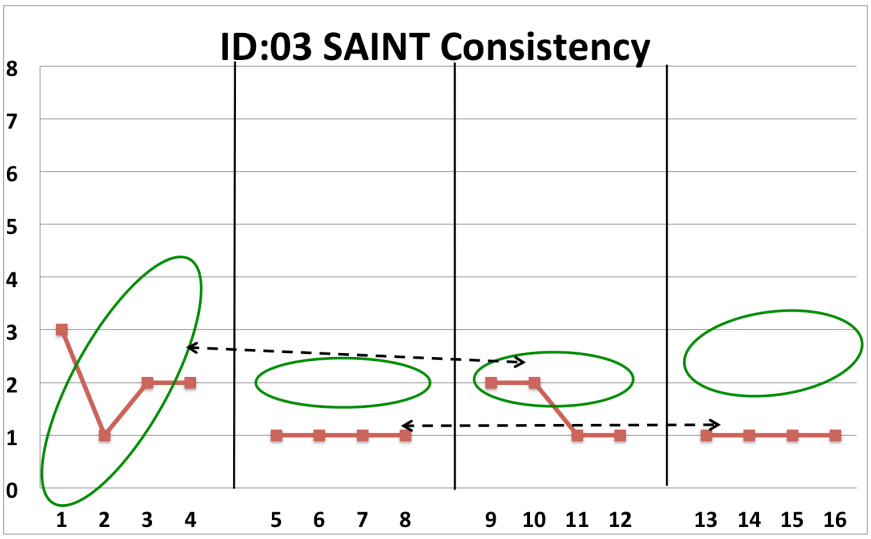
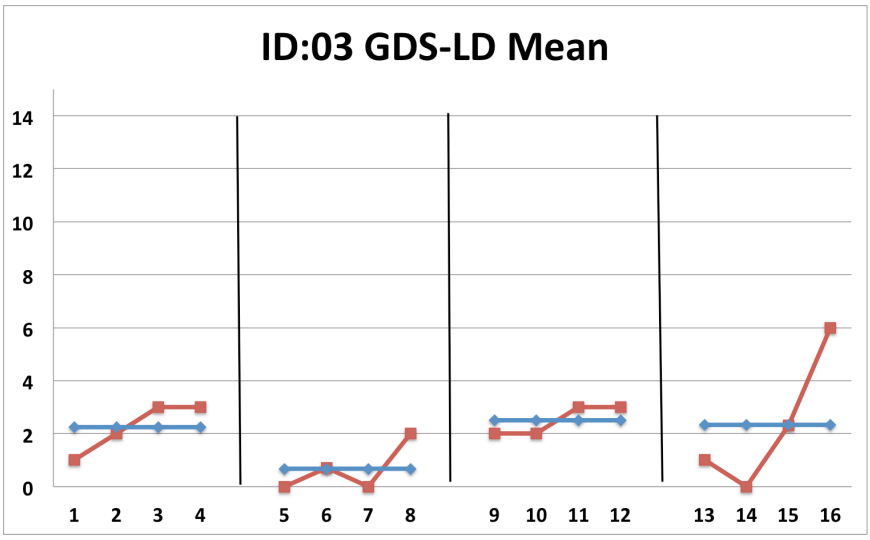
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

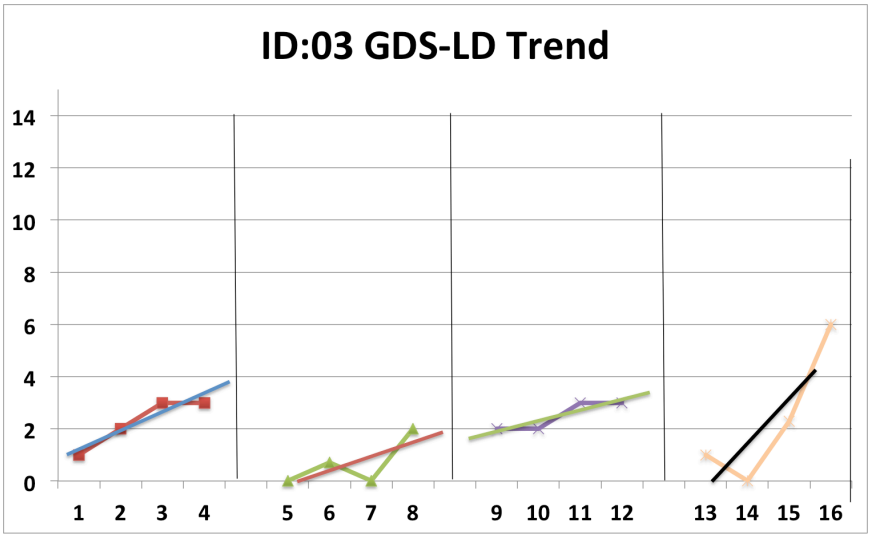

ID:03 SAINT Variability
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

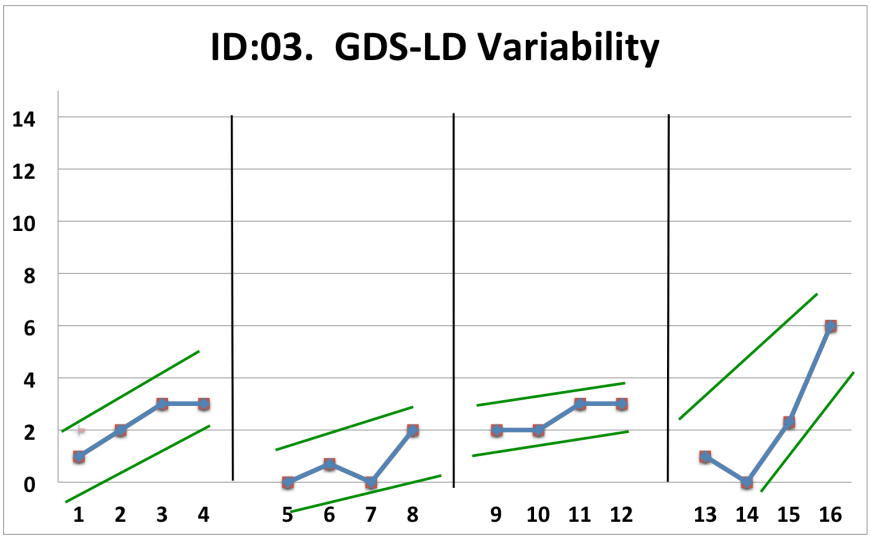

ID:03 SAINT Overlap
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

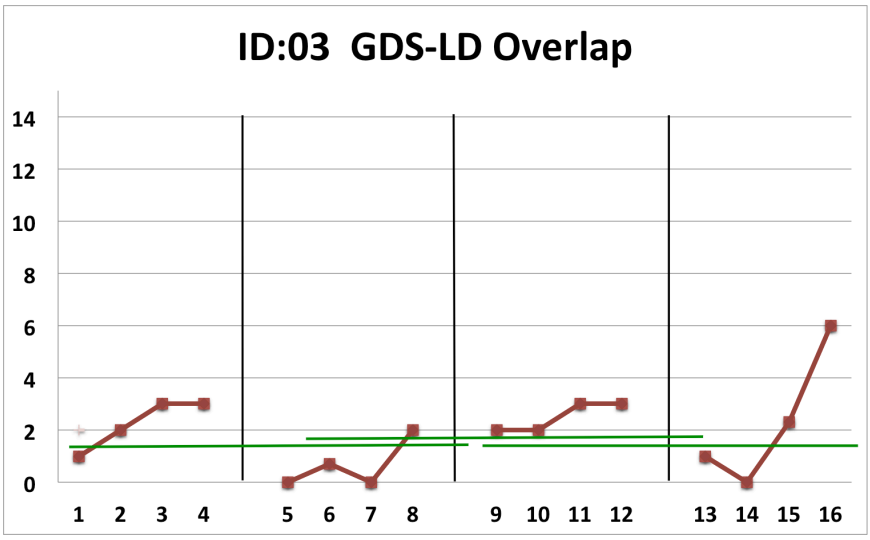

ID:03 SAINT Immediacy
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03 SAINT Consistency
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03 GDS-LD Mean
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03 GDS-LD Trend
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03. GDS-LD Variability
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03 GDS-LD Overlap
14
12
10
8
6
4
2
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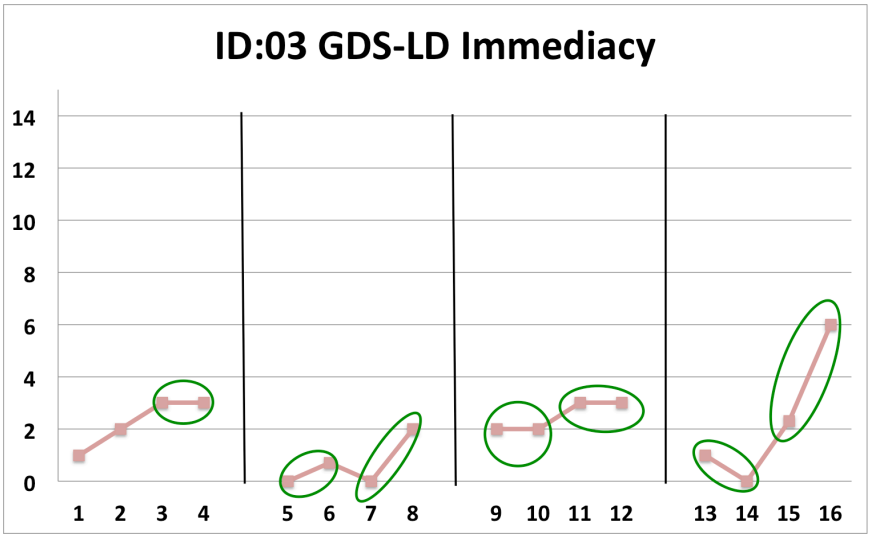
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03 GDS-LD Immediacy
14
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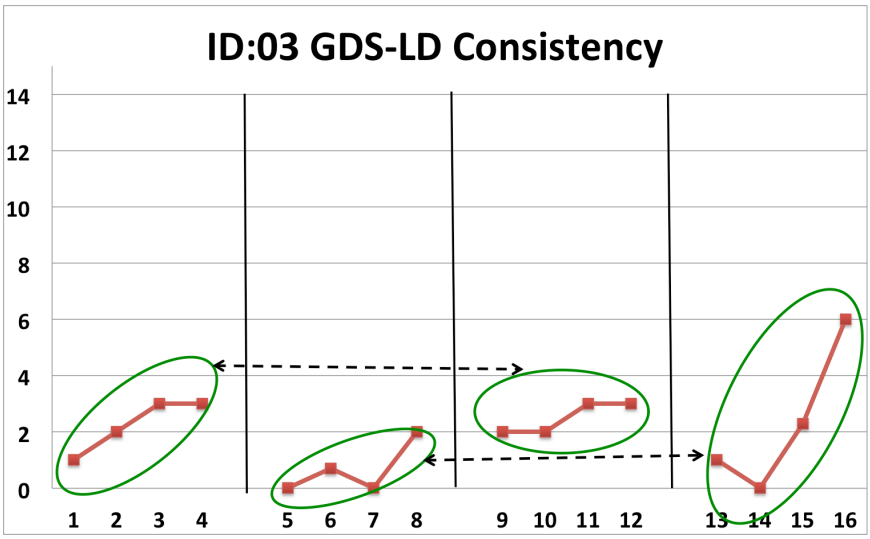
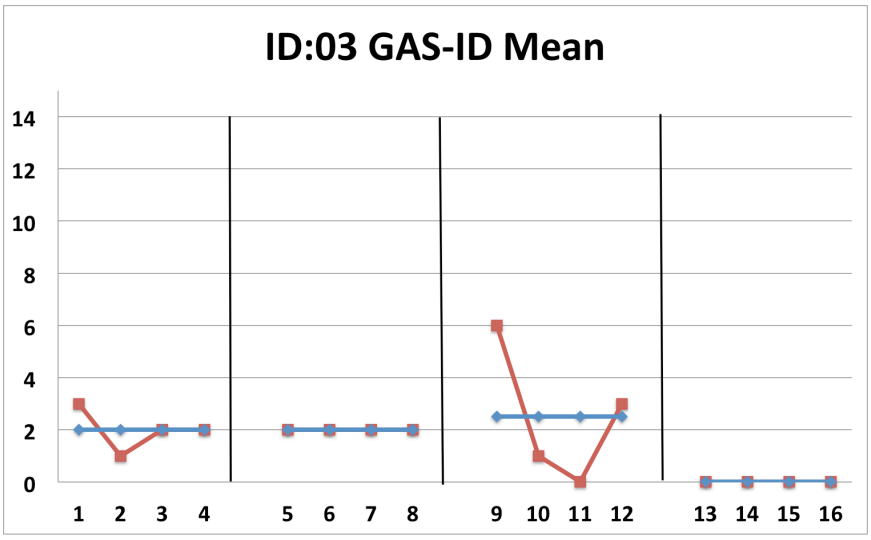
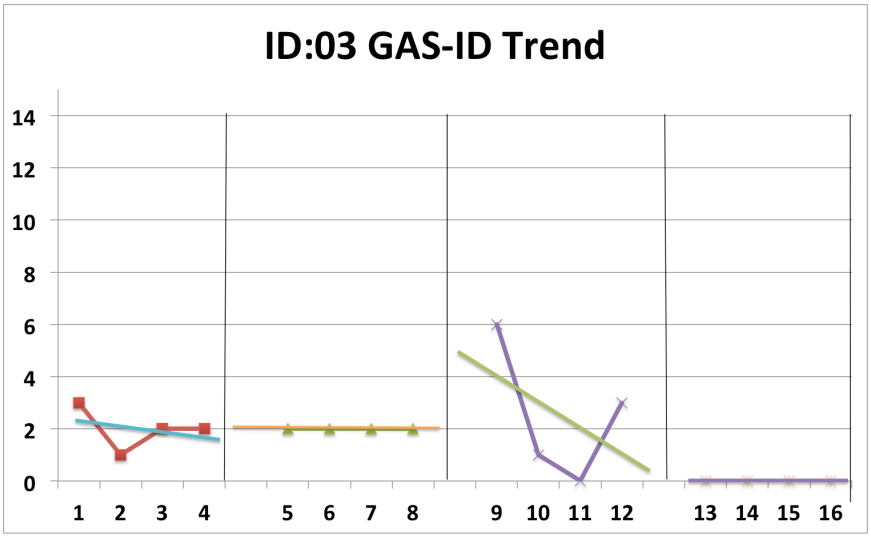
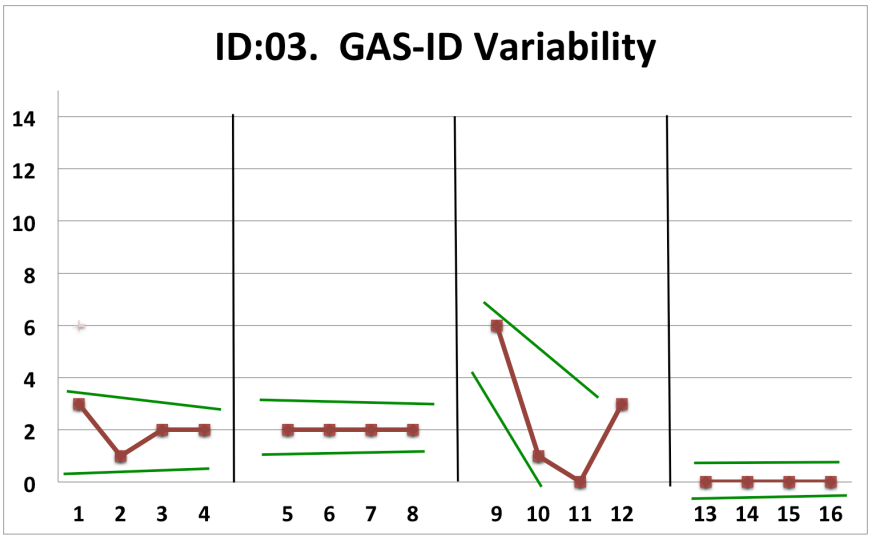
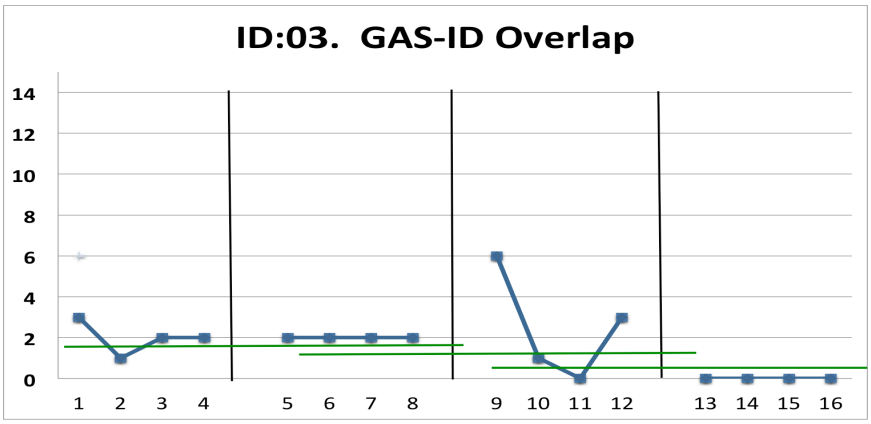
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

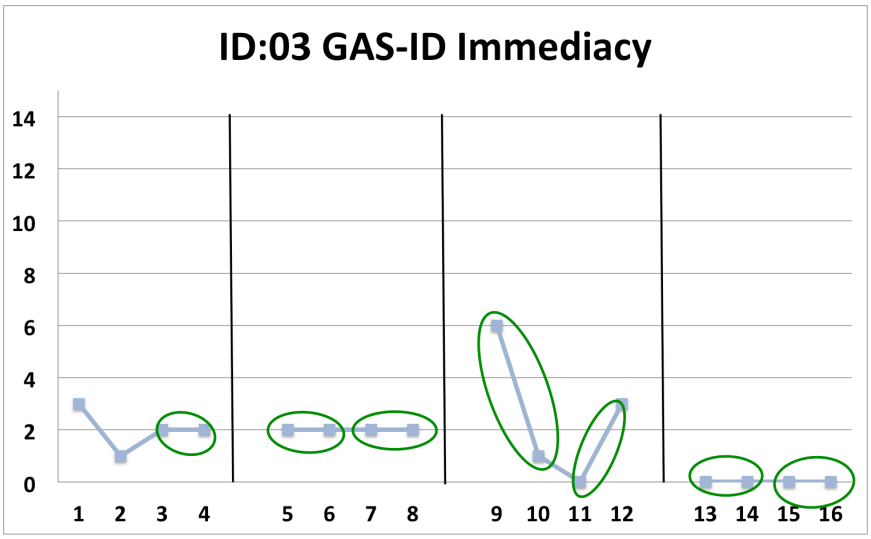

ID:03 GDS-LD Consistency
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

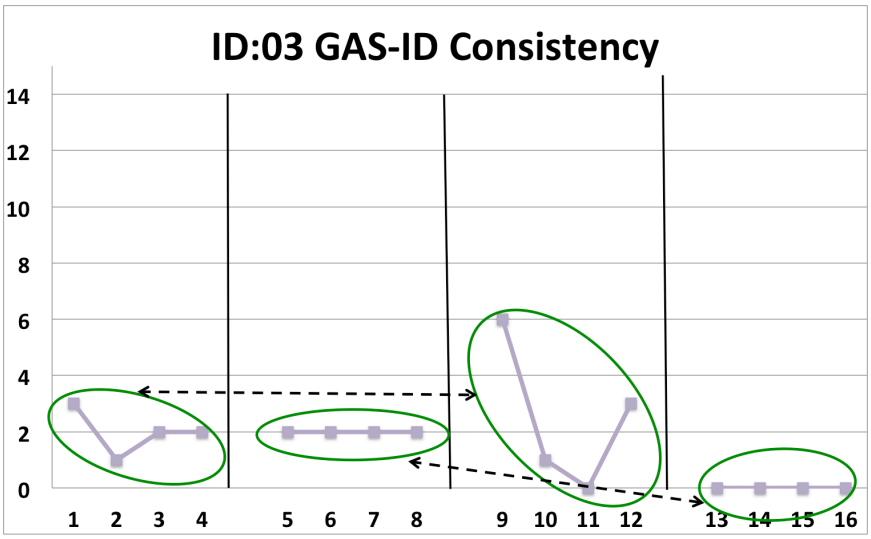

ID:03 GAS-ID Mean
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03 GAS-ID Trend
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:03. GAS-ID Variability
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

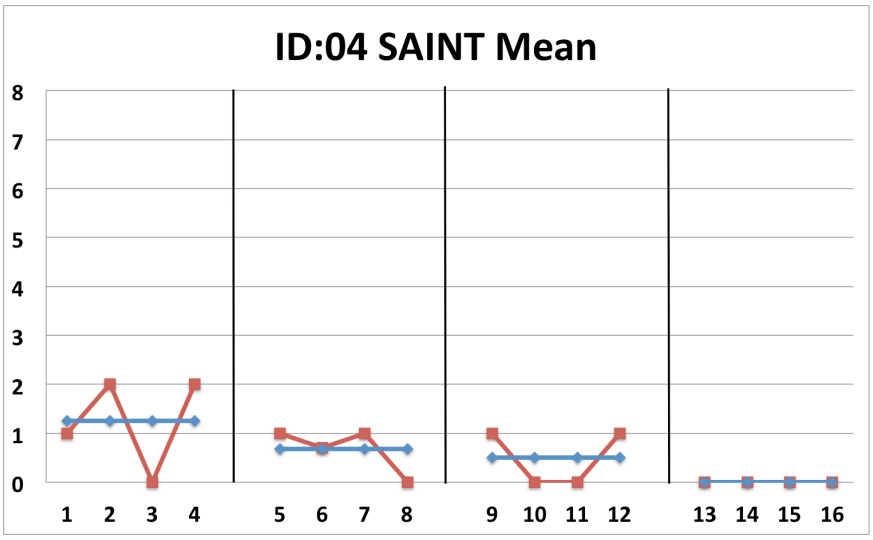

ID:03. GAS-ID Overlap
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

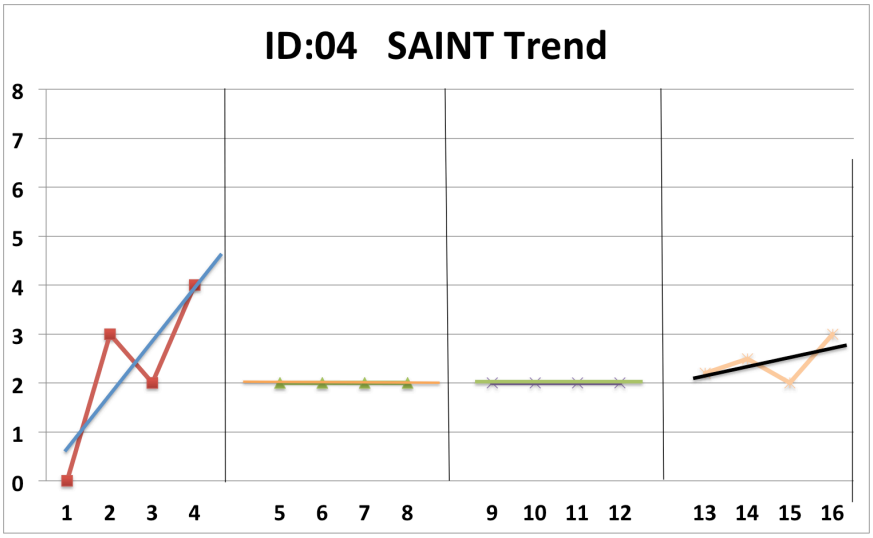

ID:03 GAS-ID Immediacy
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

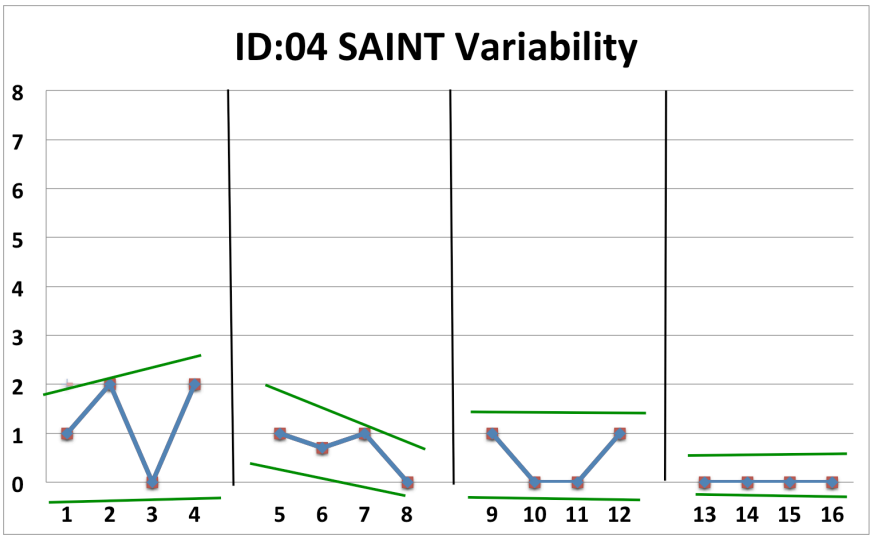

ID:03 GAS-ID Consistency
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

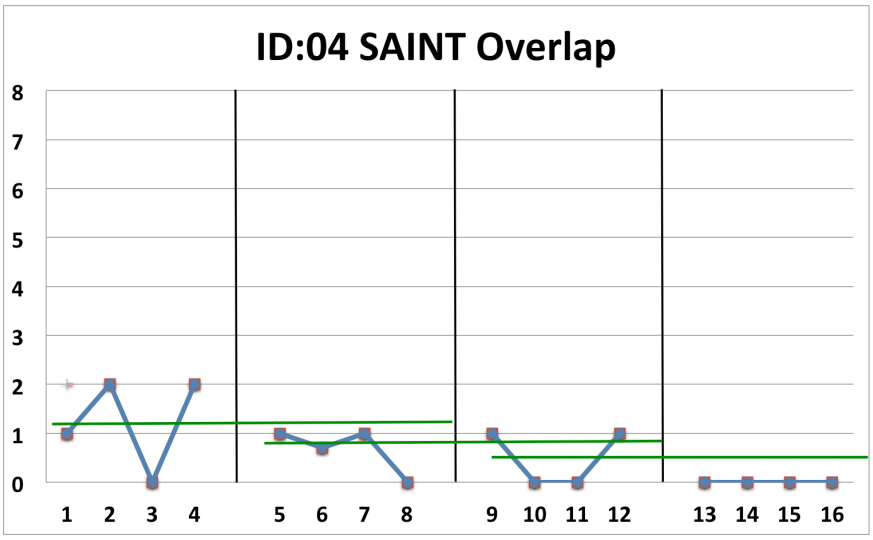
ID-4 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	1	3	4
2	2	2	2
3	0	2	0
4	2	3	1
5	1	3	1
6	**0.7**	**2**	**1.7**
7	1	3	3
8	0	0	1
9	1	1	2
10	0	0	1
11	0	0	1
12	1	2	1
13	0	0	1
14	0	0	1
15	**0**	**0.3**	**0.7**
16	0	1	0


ID:04 SAINT Mean
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:04 SAINT Trend
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:04 SAINT Variability
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:04 SAINT Overlap
8
7
6
5
4
3
2
1
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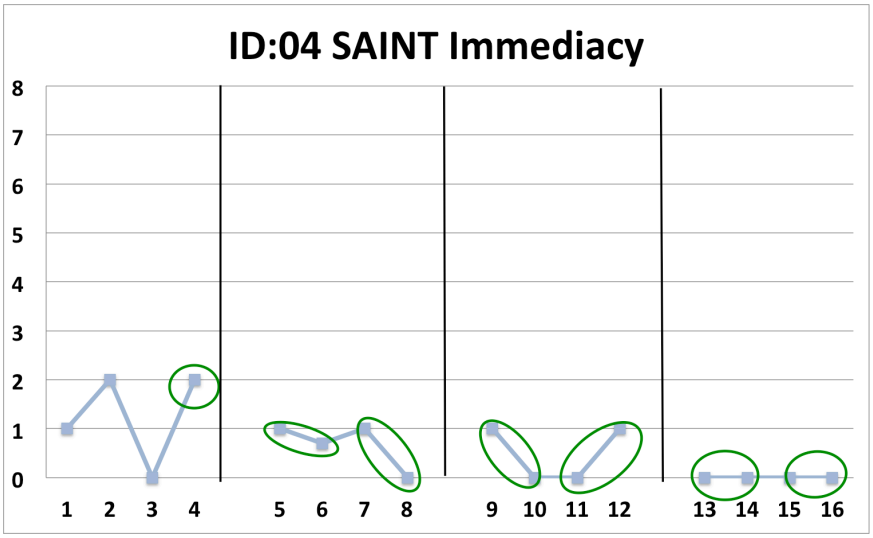
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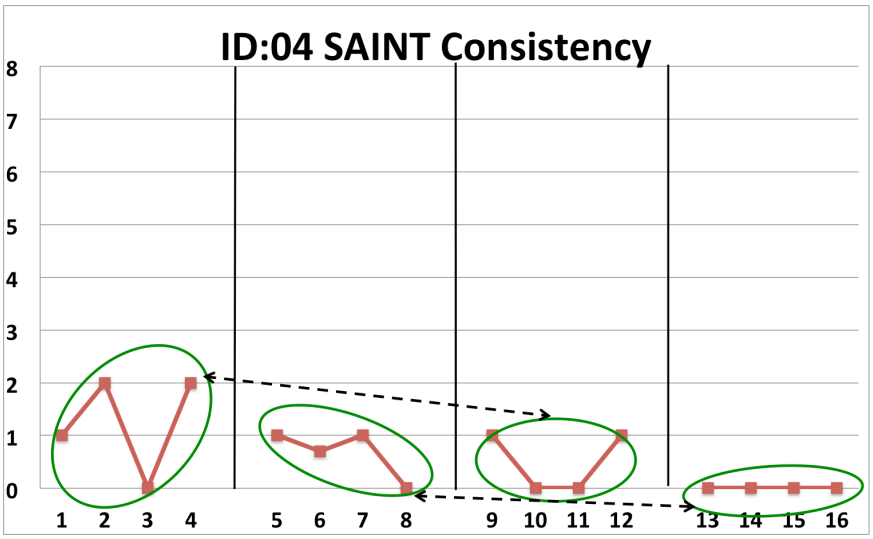
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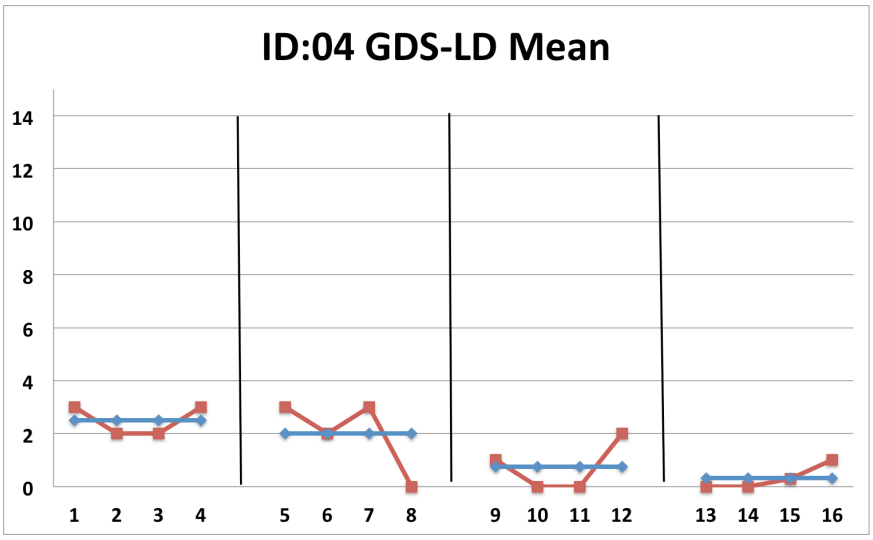
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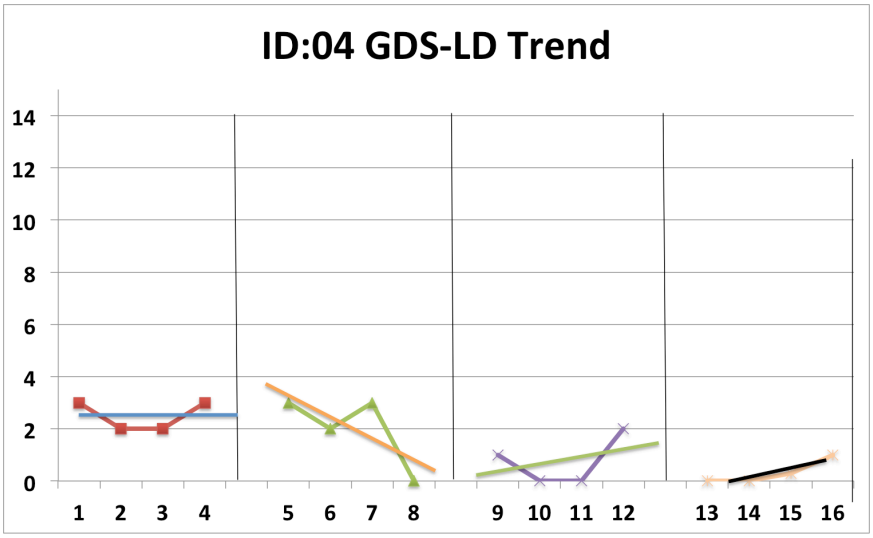
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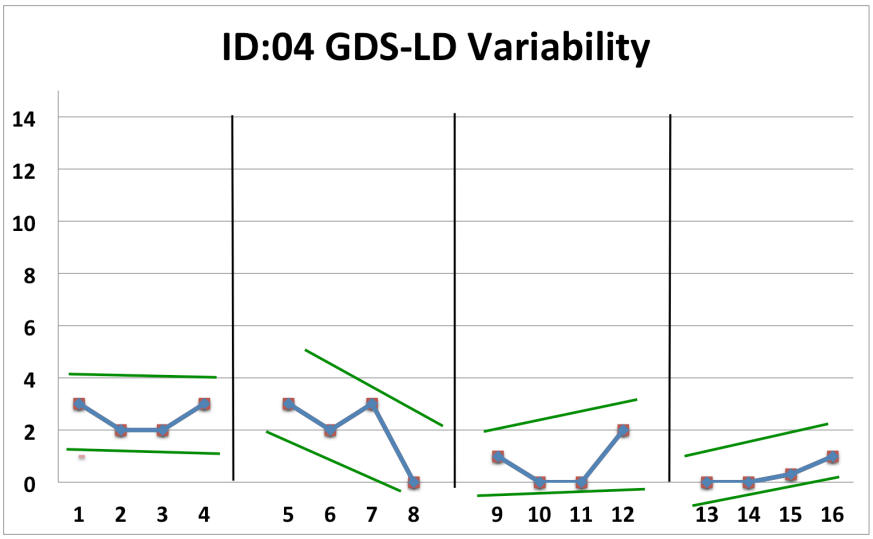
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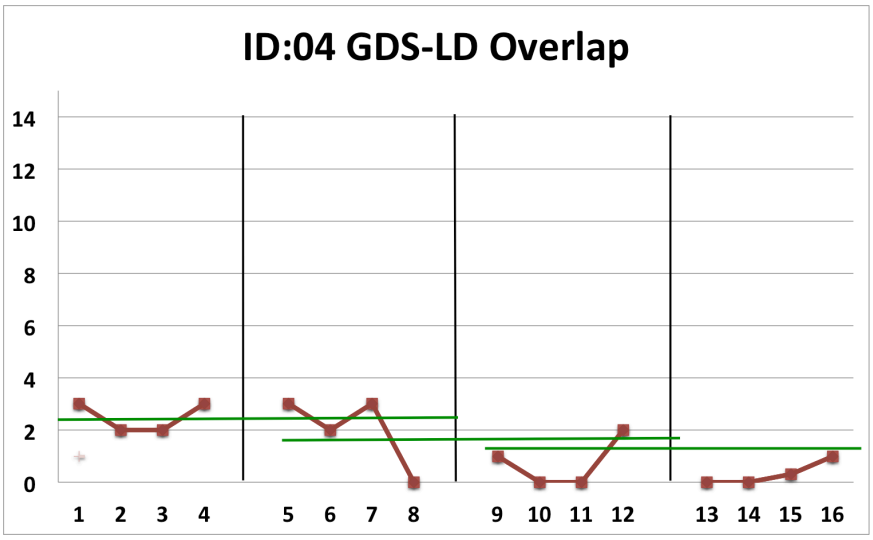
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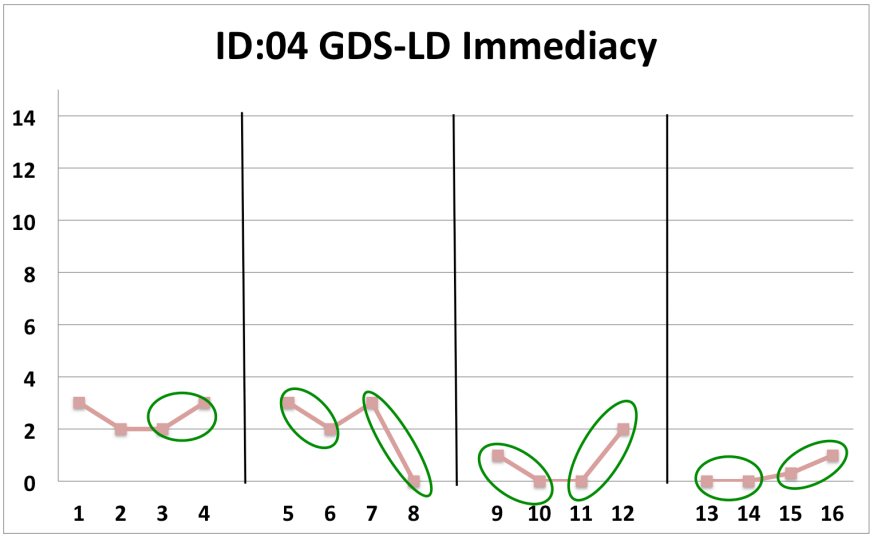
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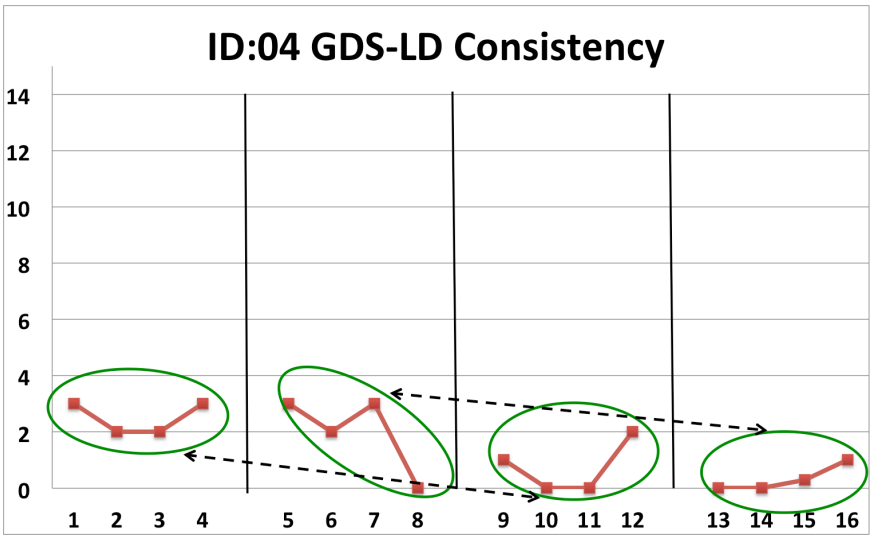
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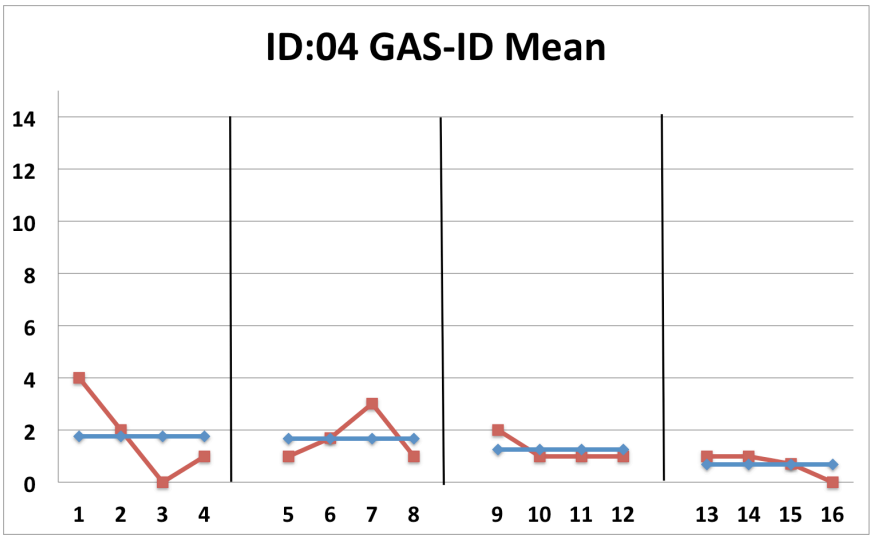
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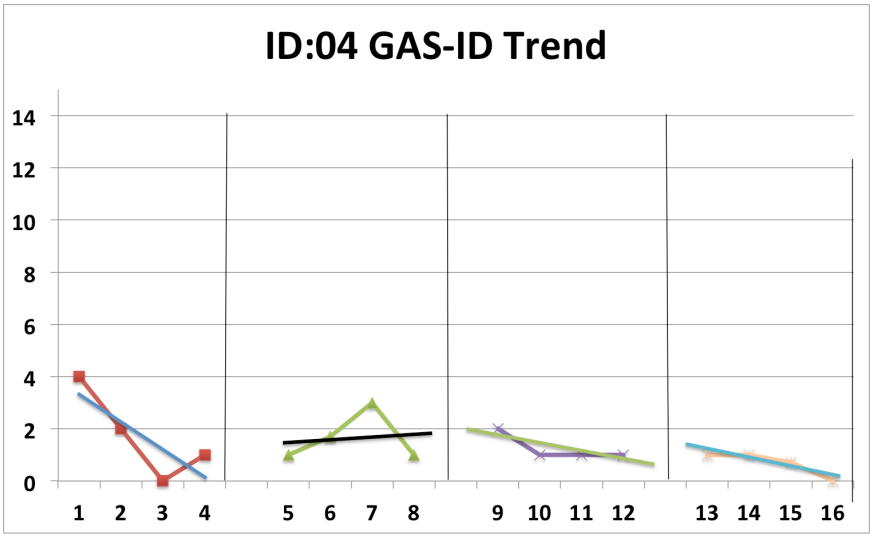
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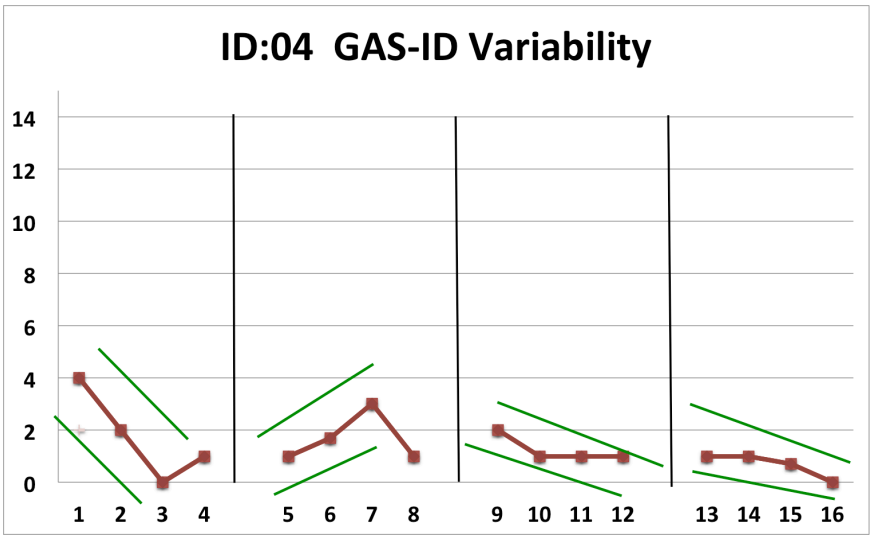
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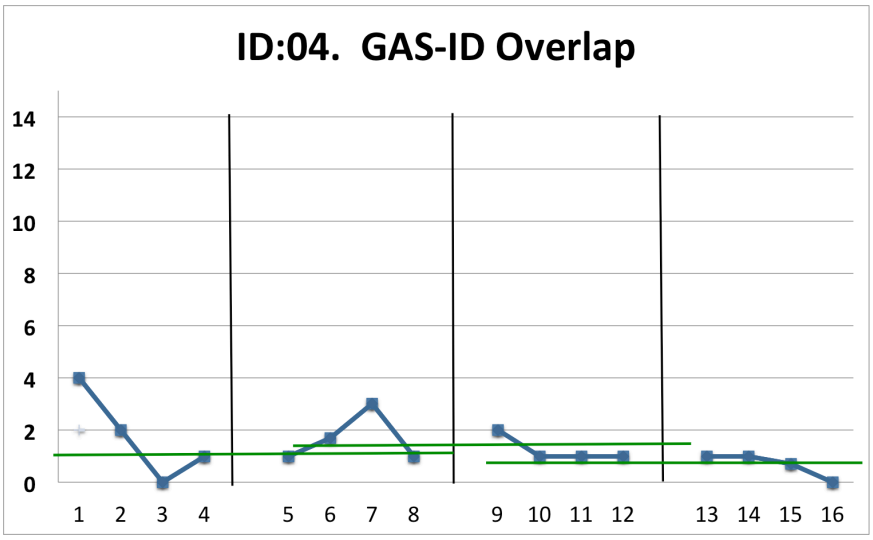
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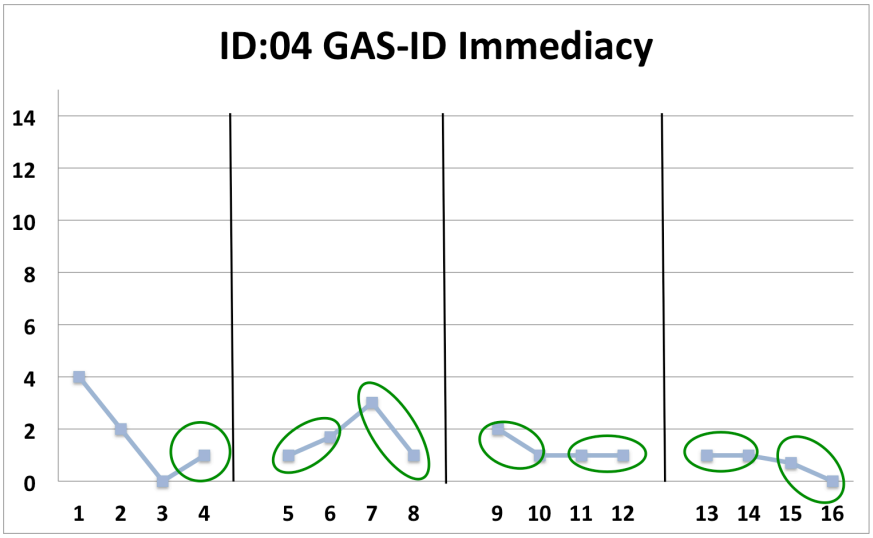
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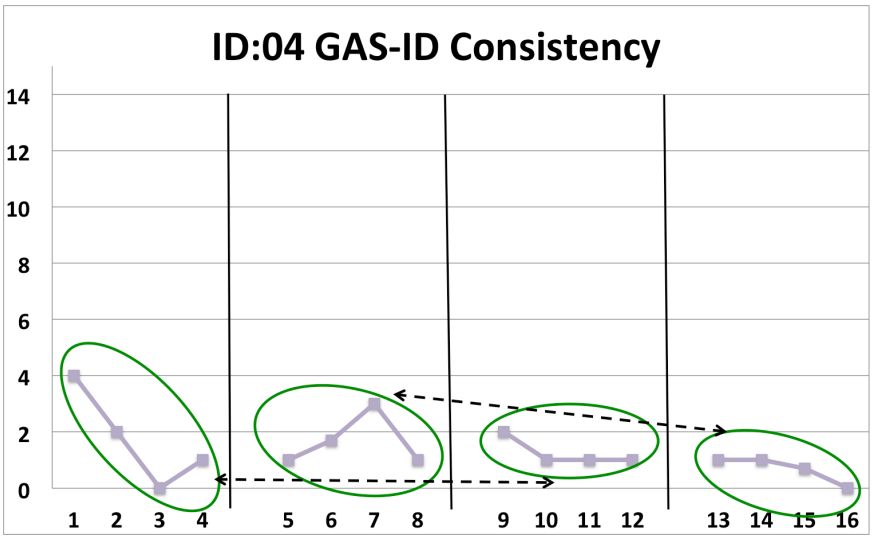
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week	SAINT	GDS-LD	GAS-ID
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2	3	4	3
3	3	6	2
4	3	6	2
5	2	5	5
6	**3**	**5**	**5**
7	3	5	6
8	4	5	4
9	3	6	1
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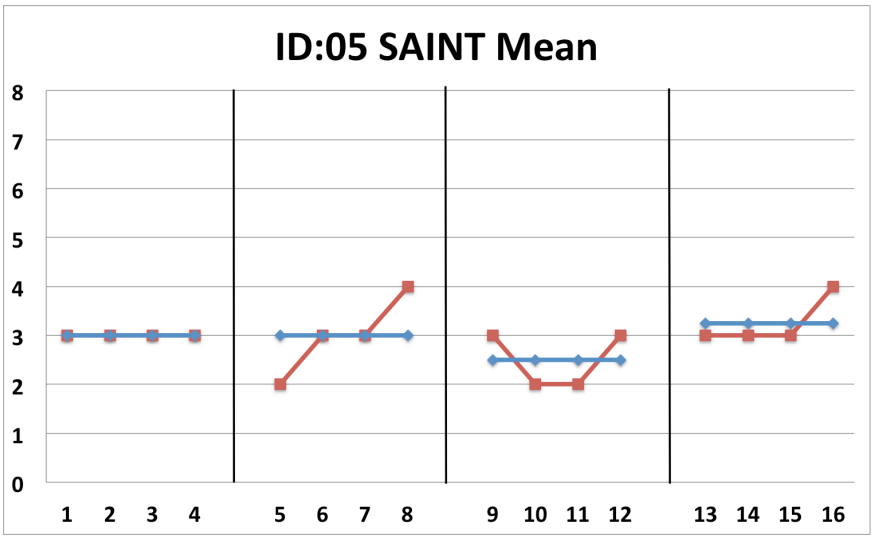
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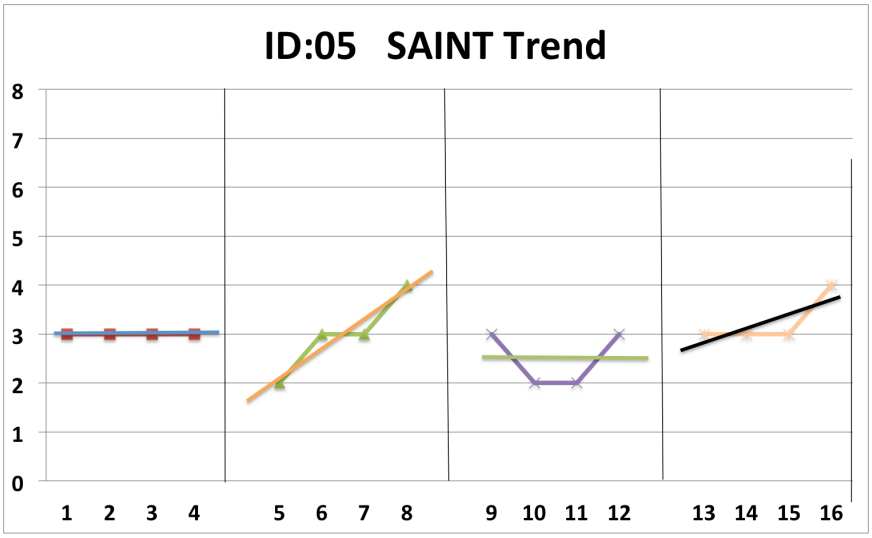
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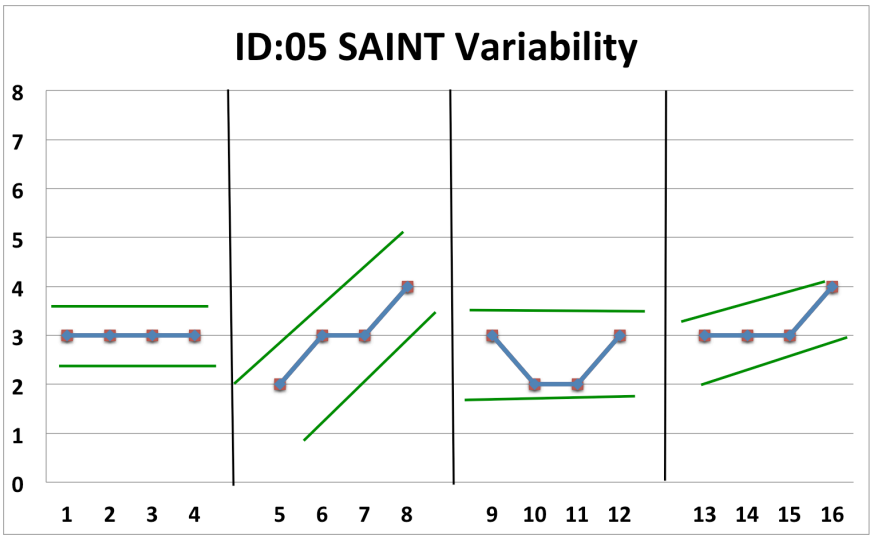
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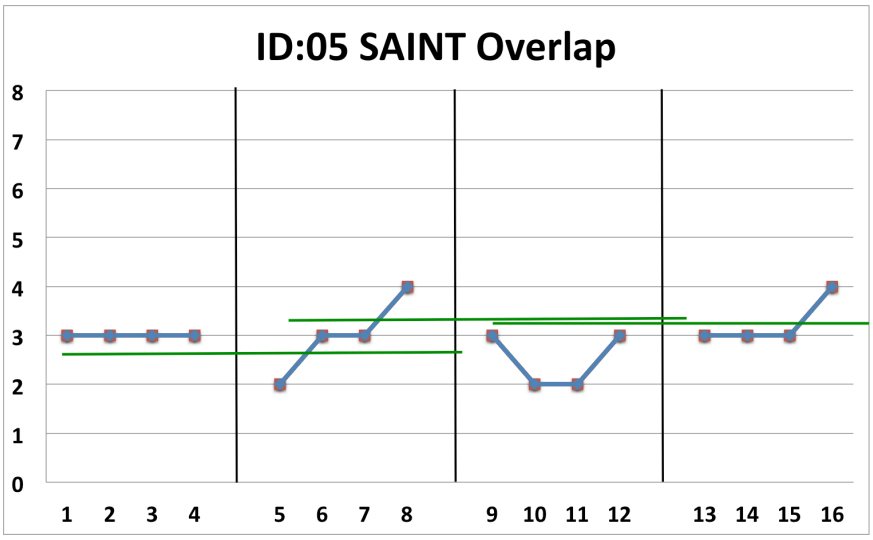
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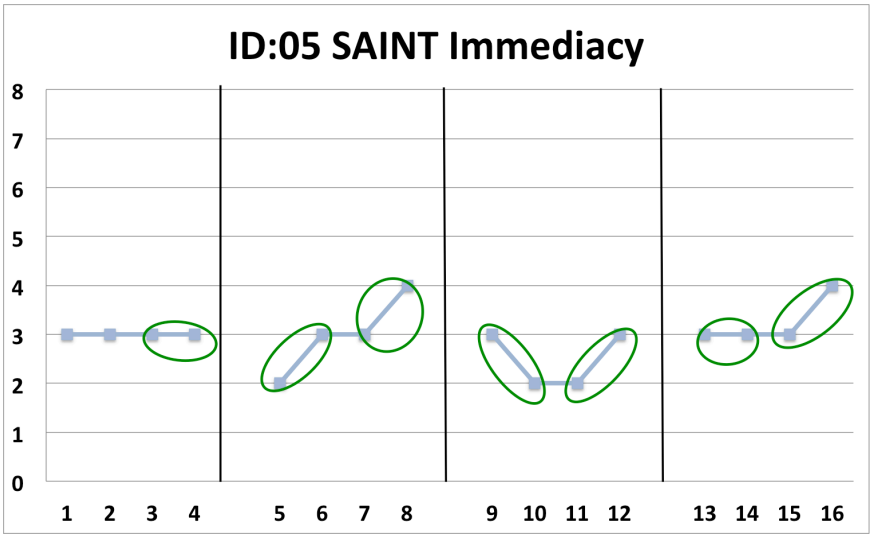
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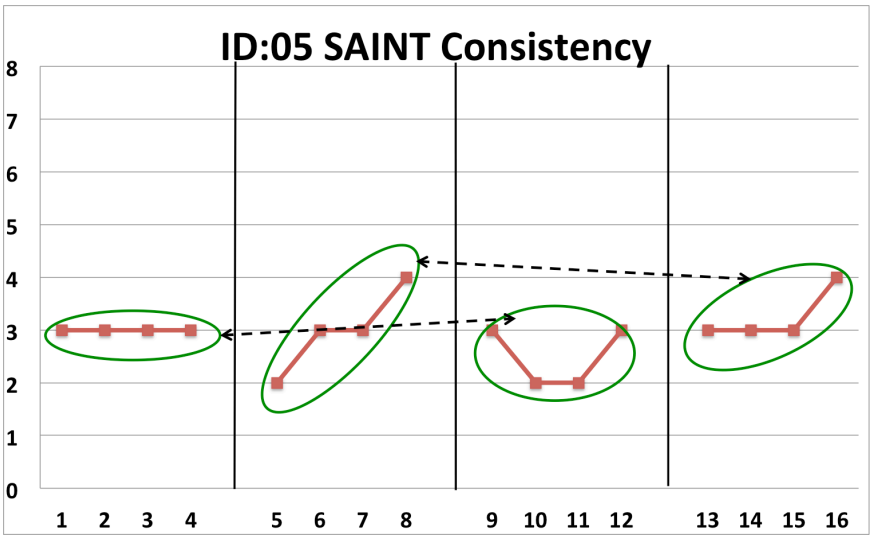
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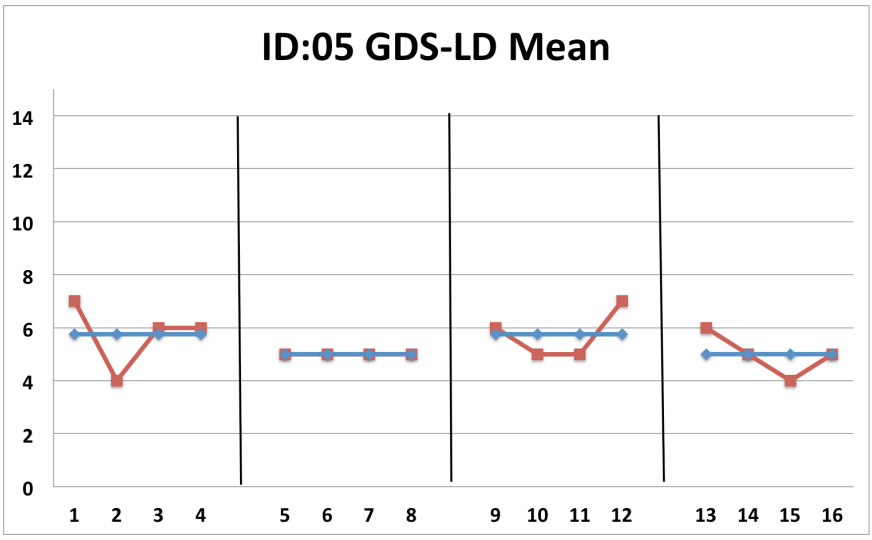
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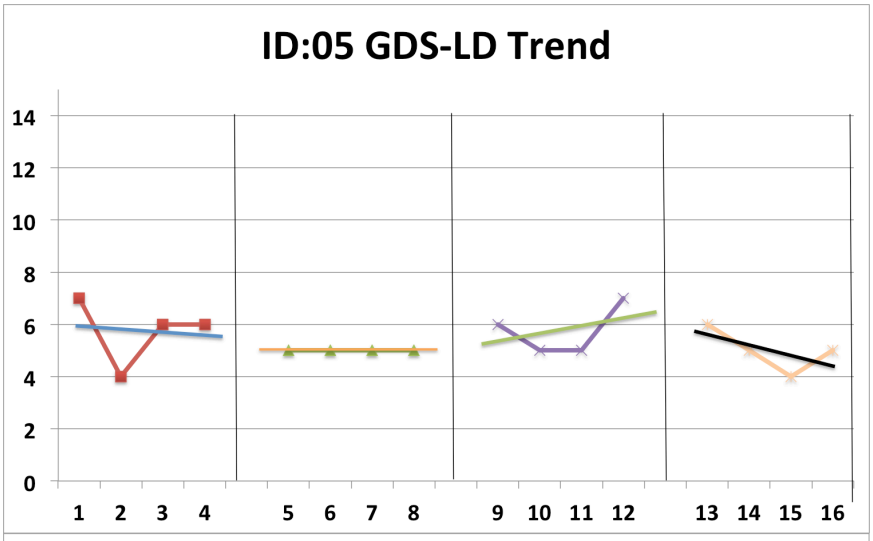
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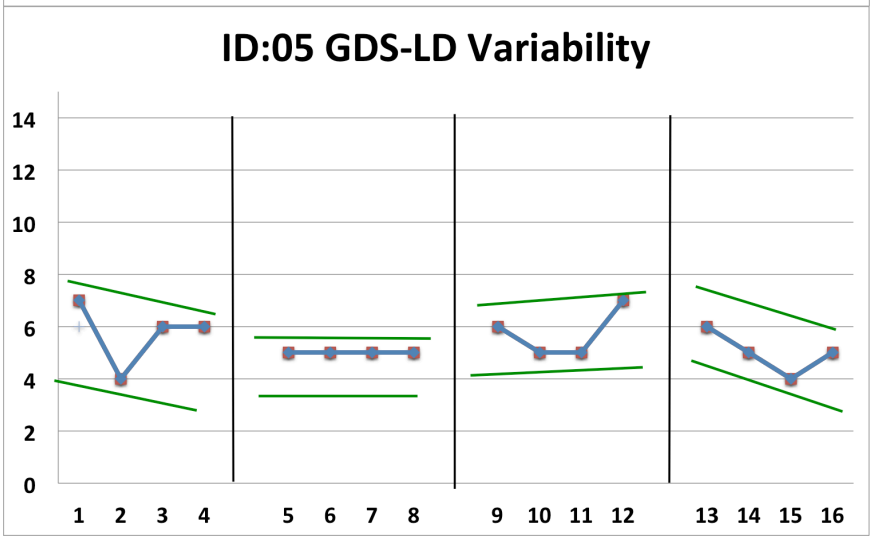
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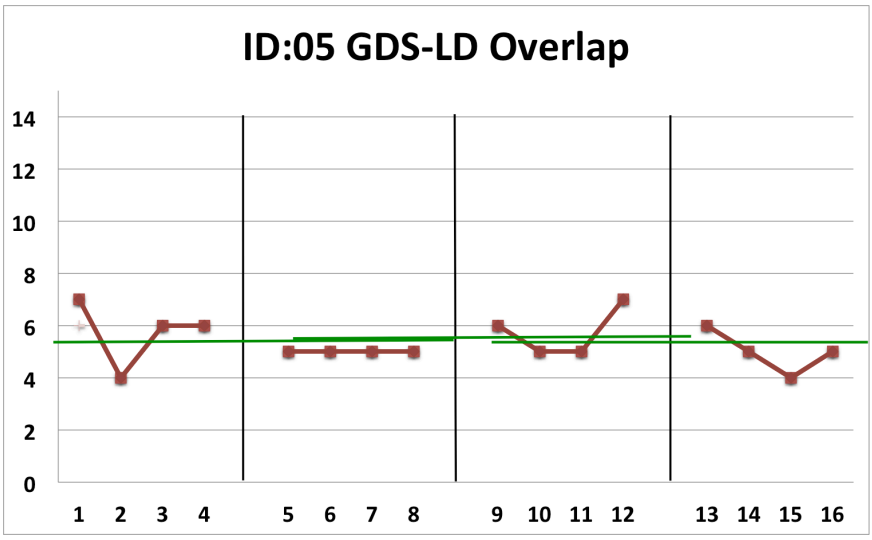
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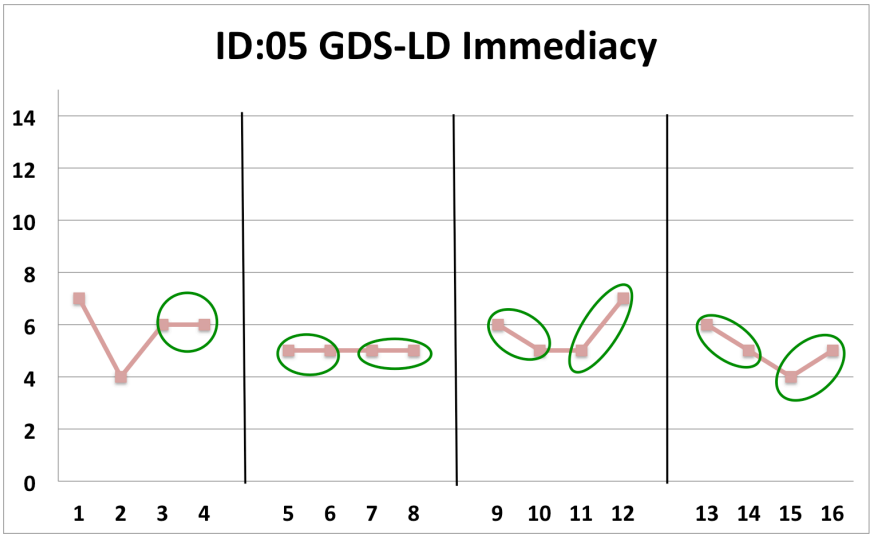
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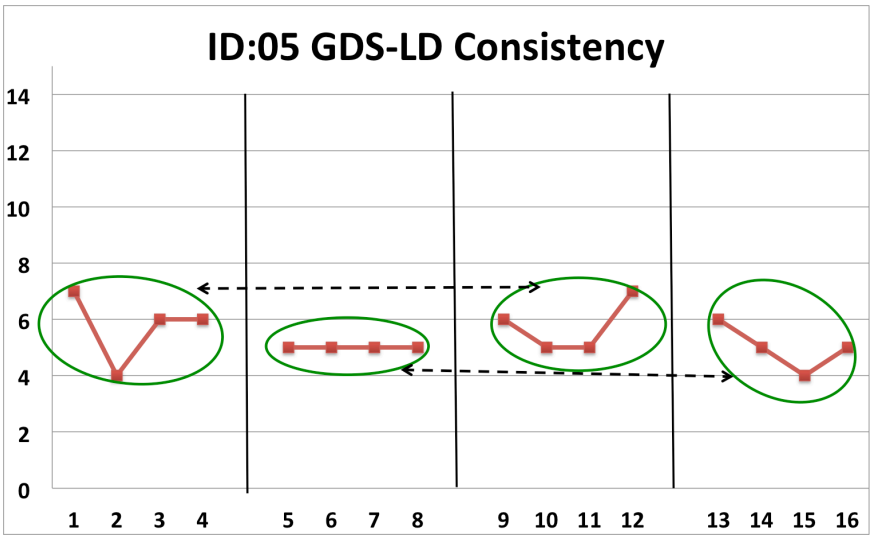
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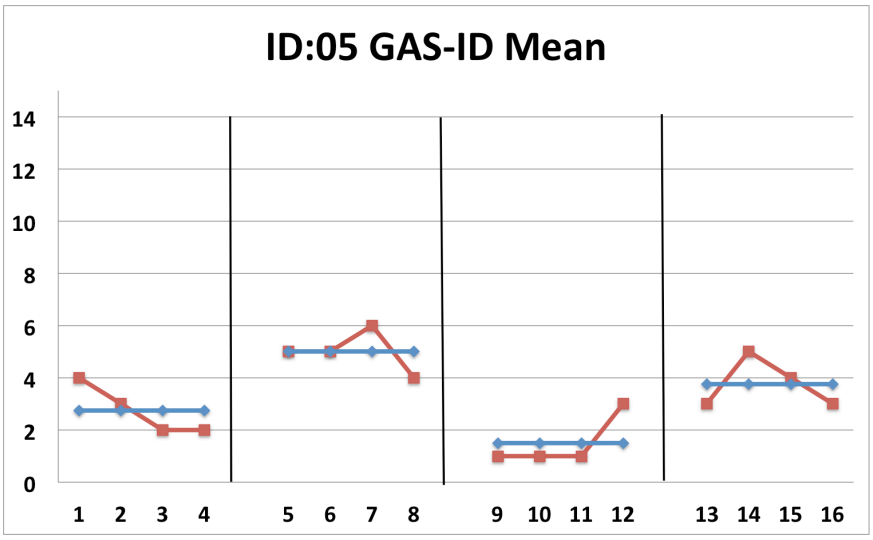
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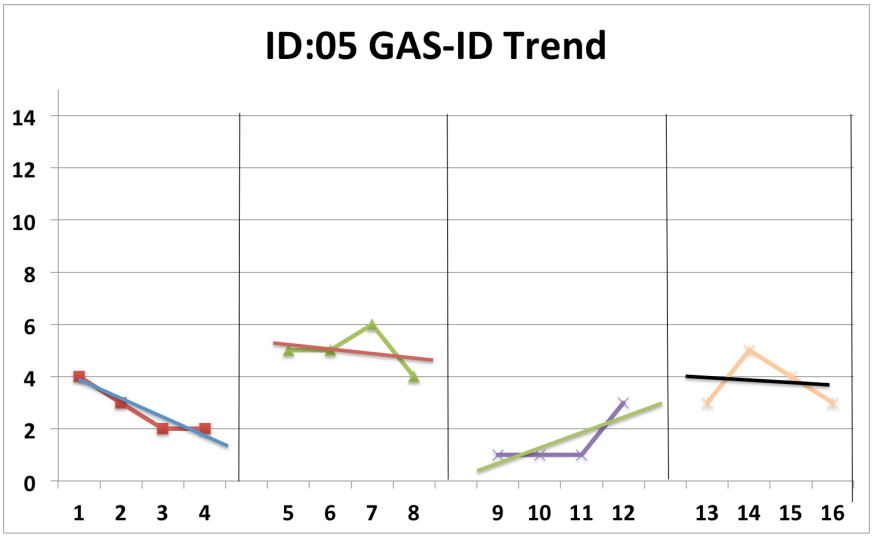
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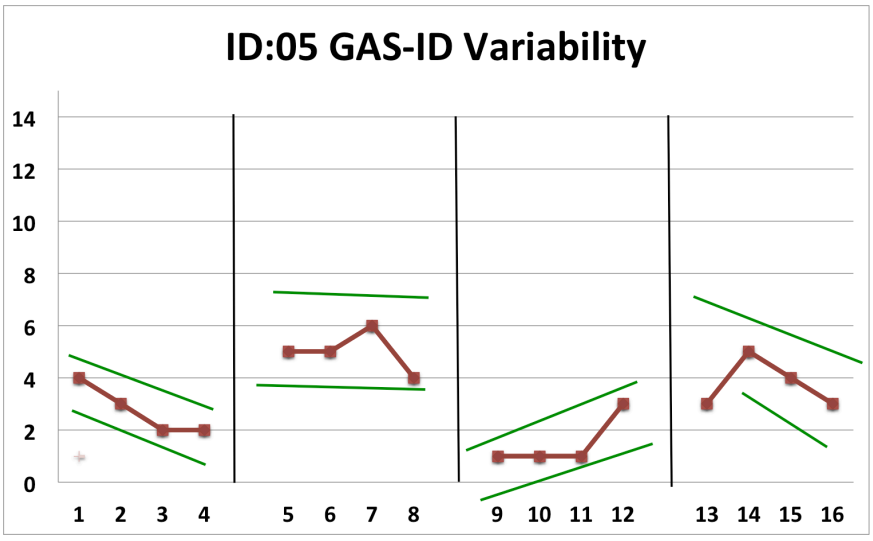
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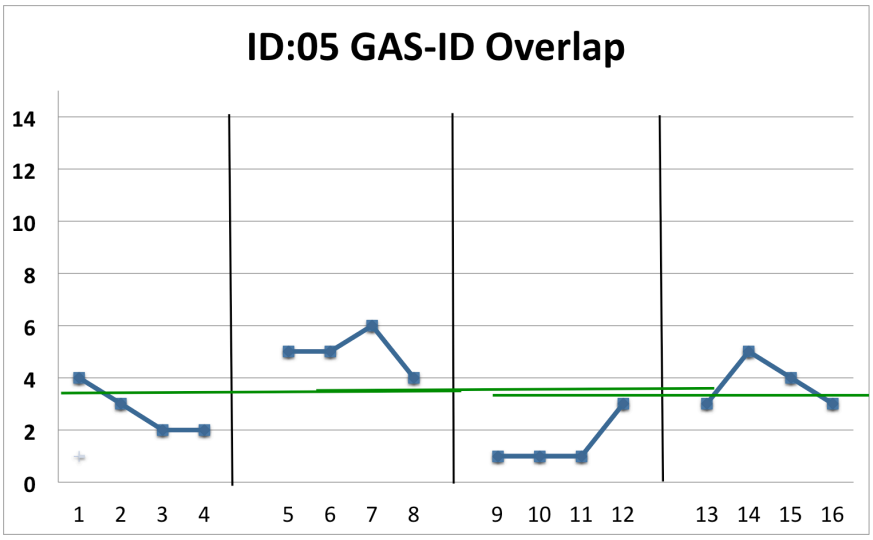
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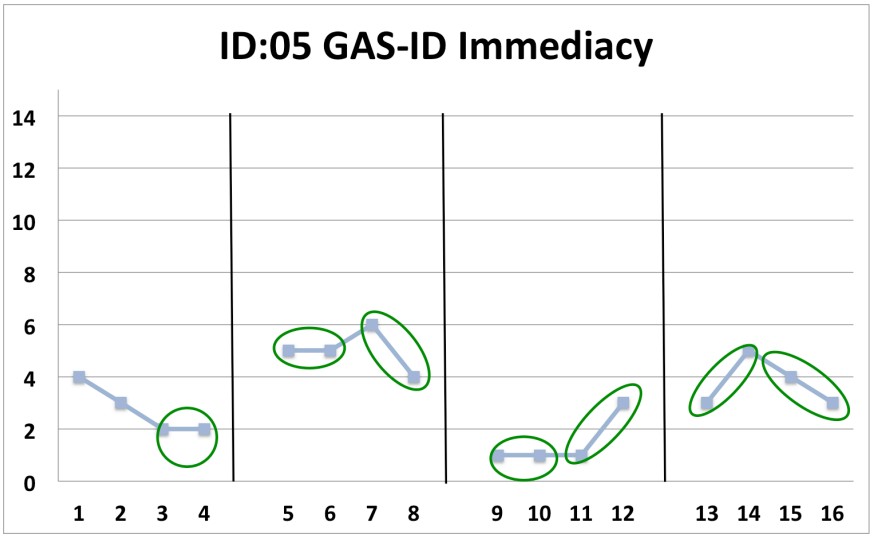
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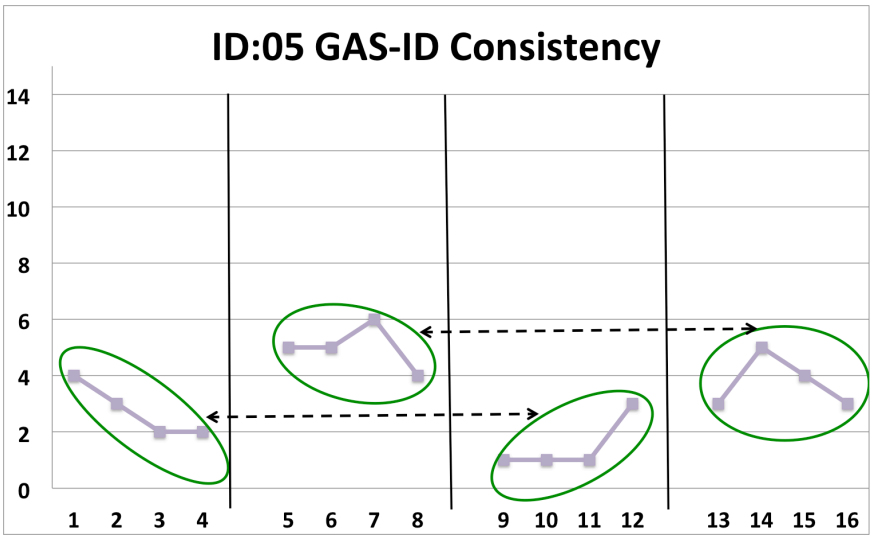
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ID-6 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	4	5	6
2	2	5	1
3	1	2	1
4	1	0	1
5	1	4	6
6	1	3	2
7	0	0	1
8	1	4	2
9	2	2	0
10	0	2	0
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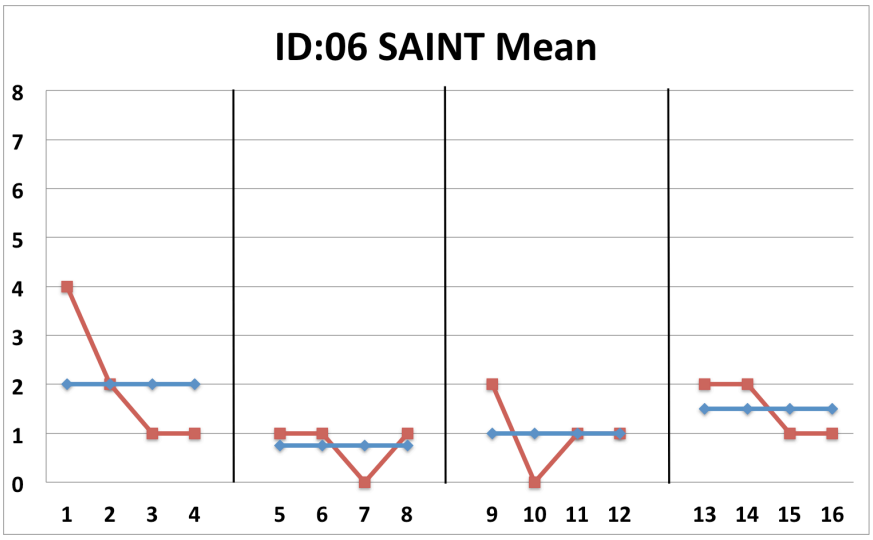
16	1	2	0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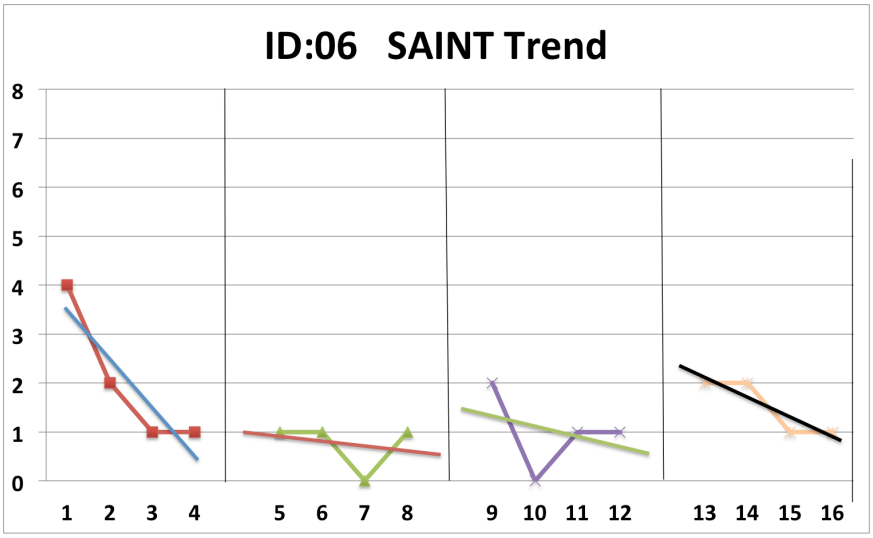
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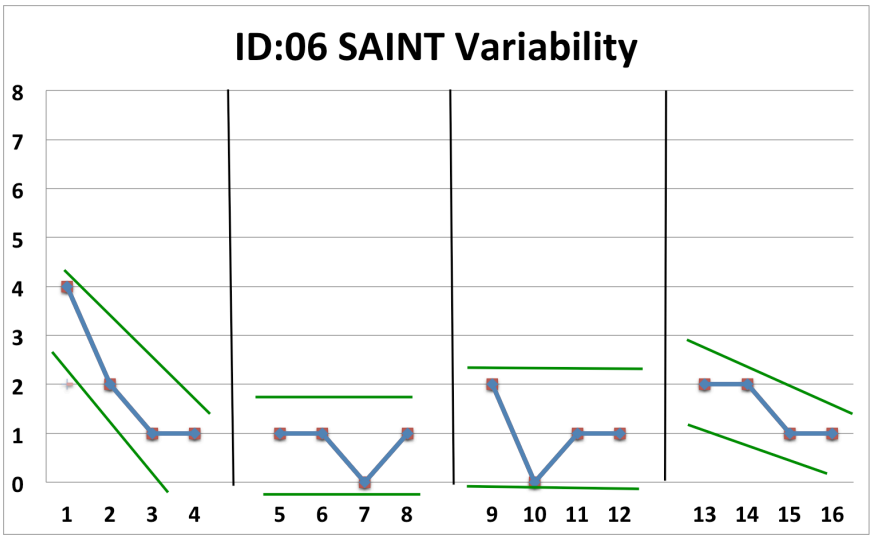
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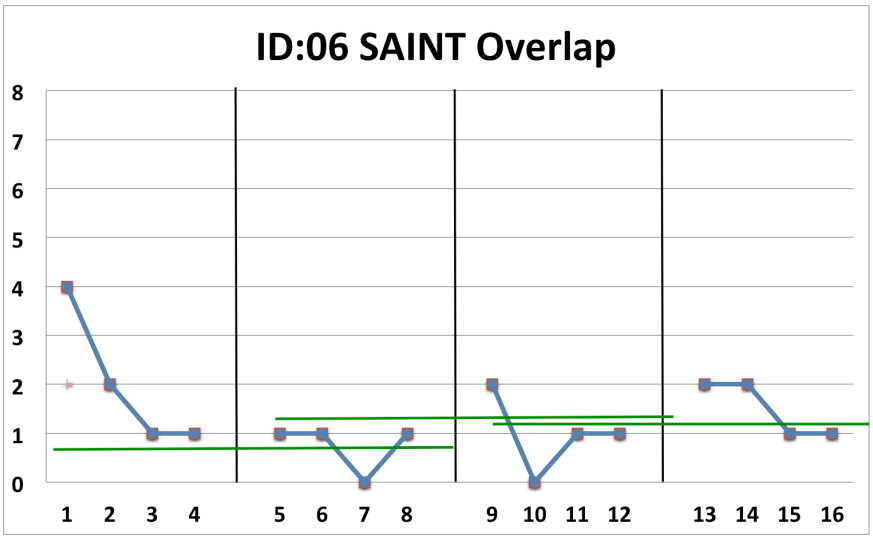
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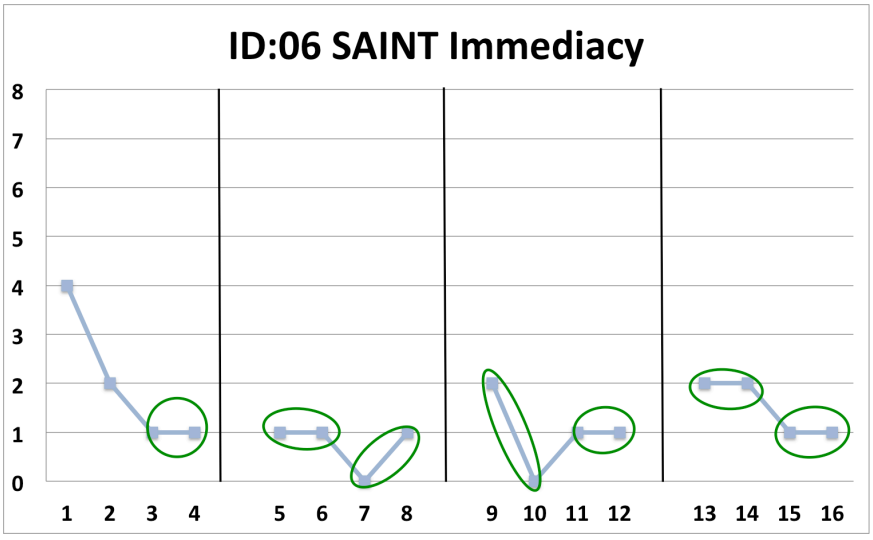
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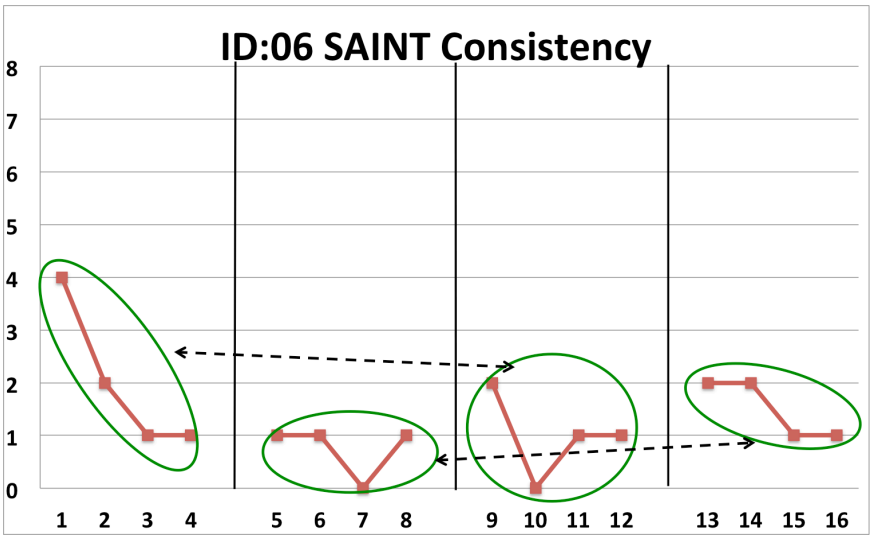
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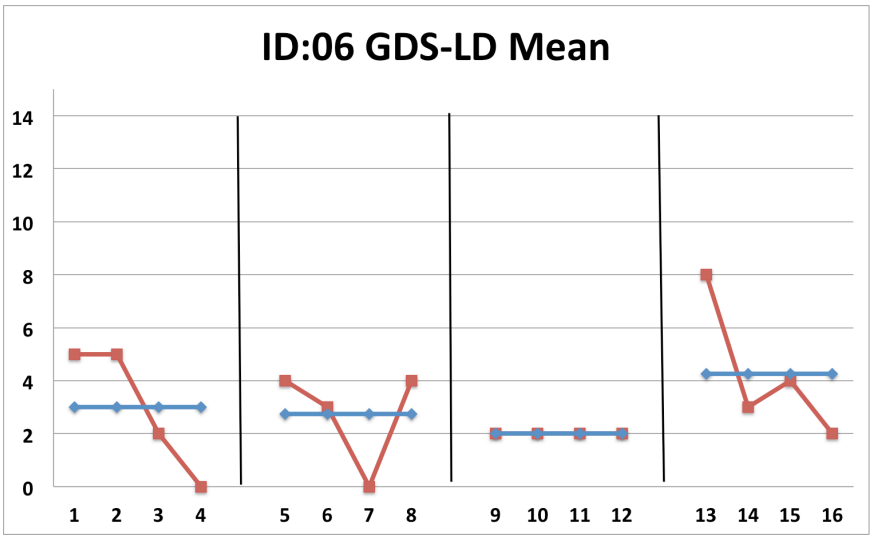
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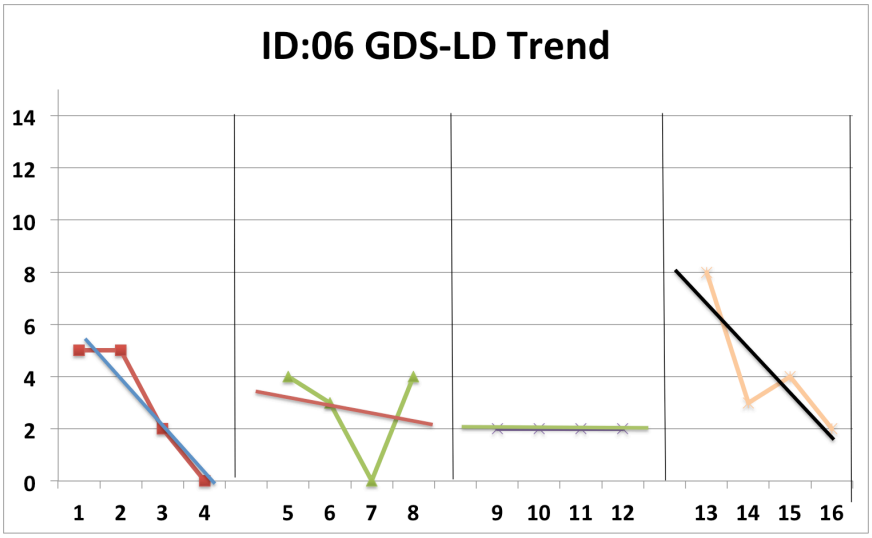
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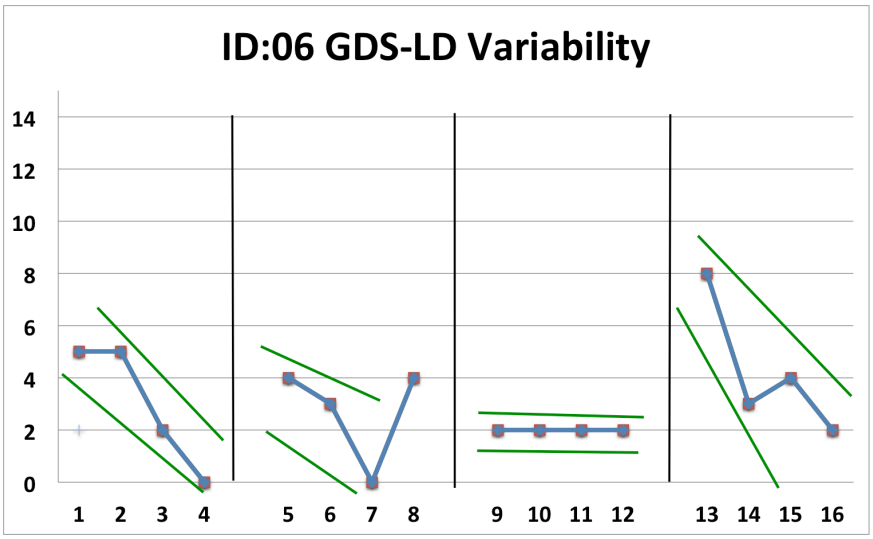
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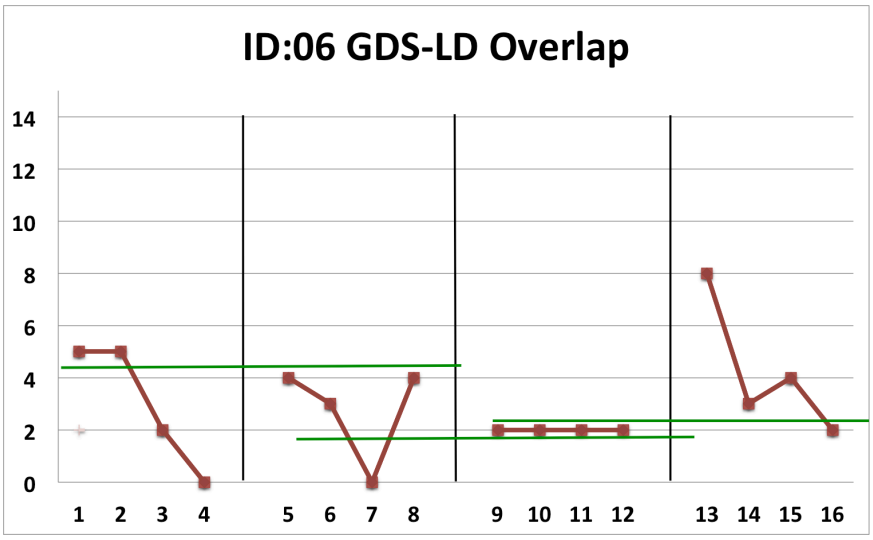
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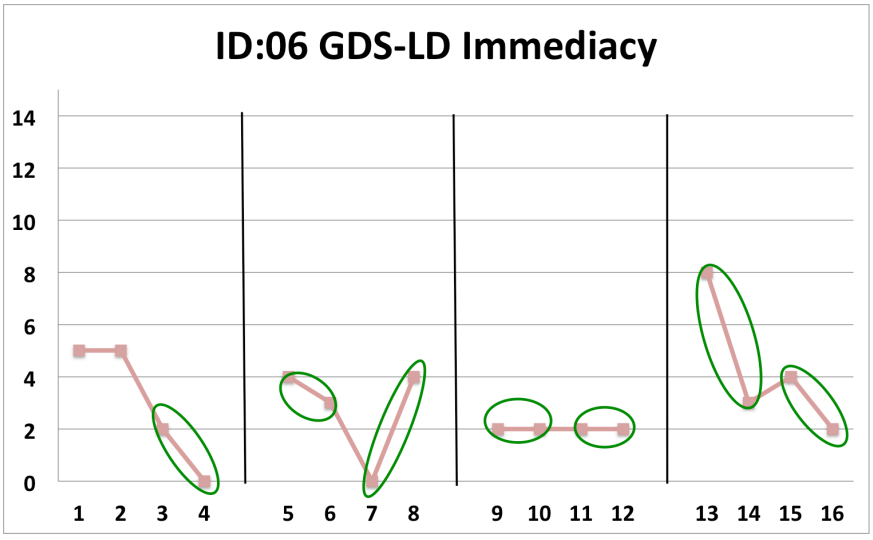
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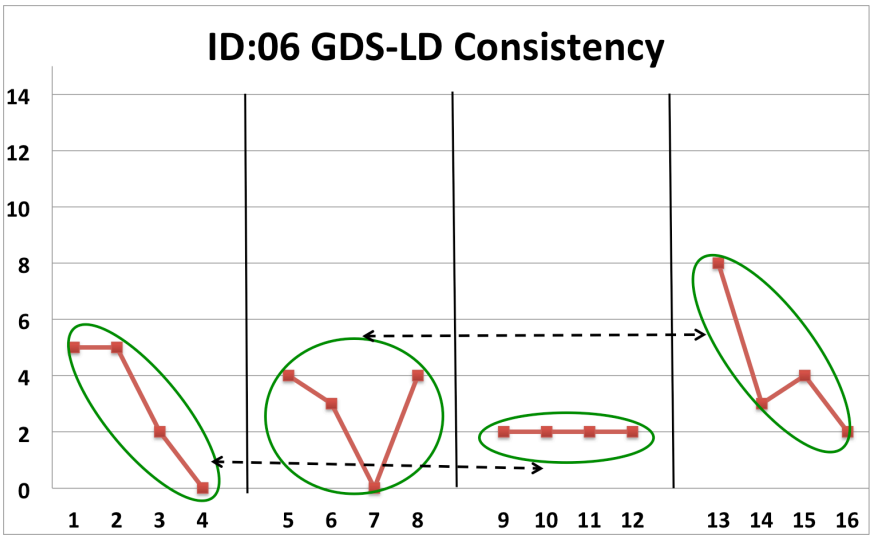
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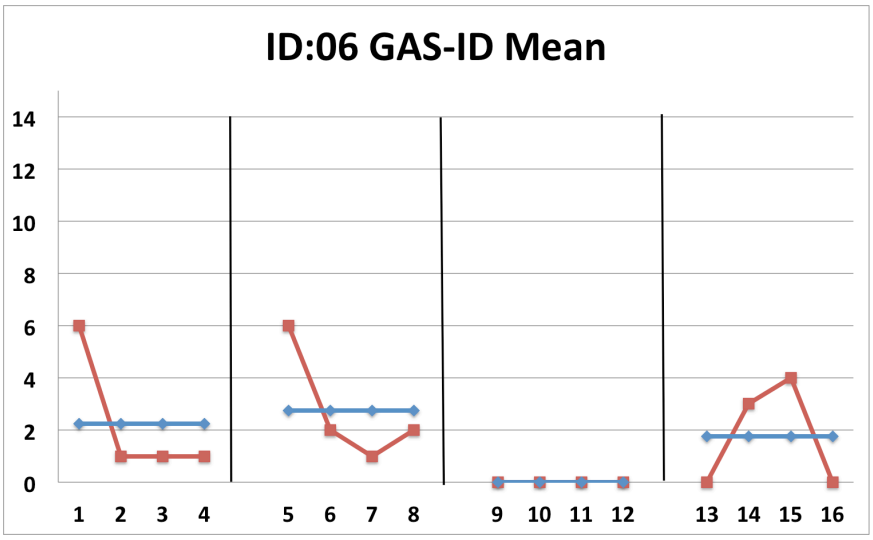
ID:06 GAS-ID Mean
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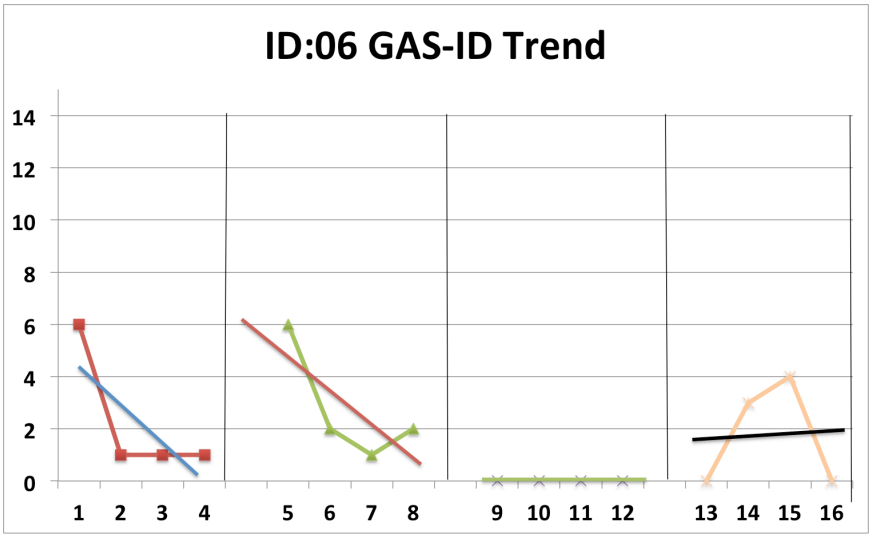
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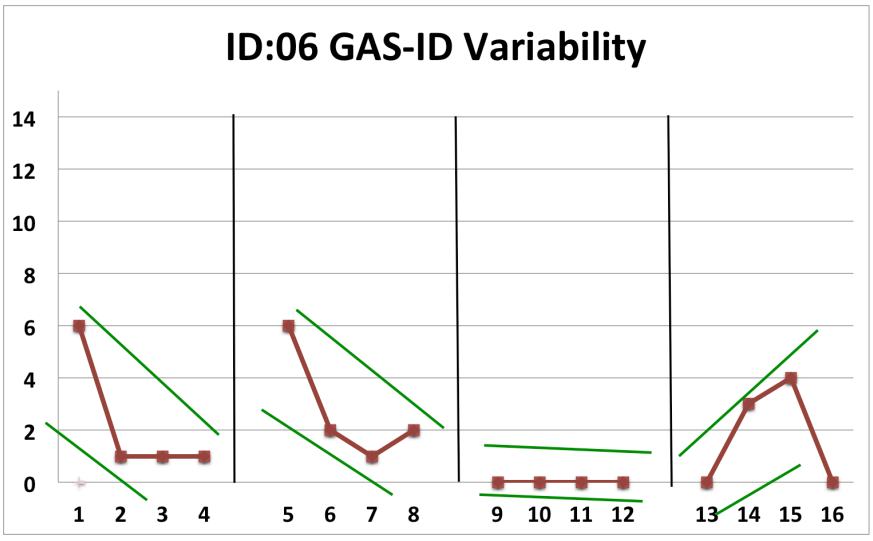
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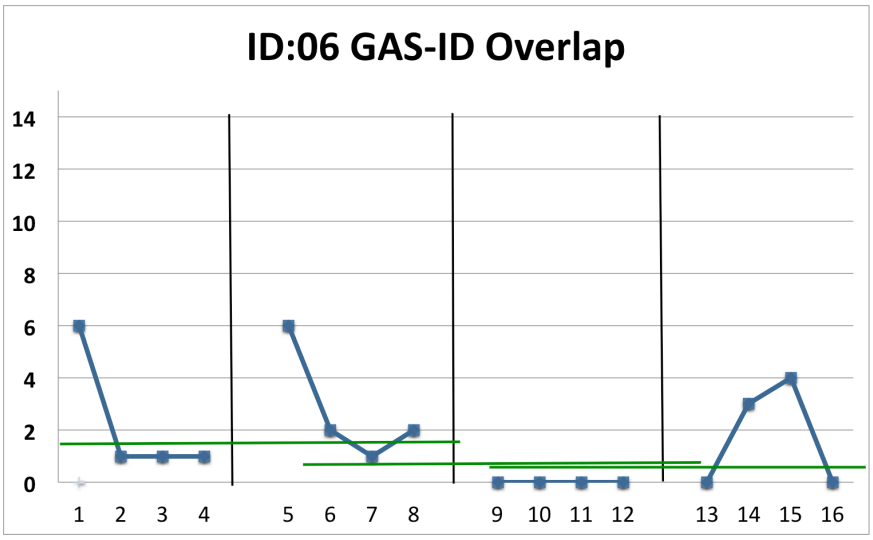
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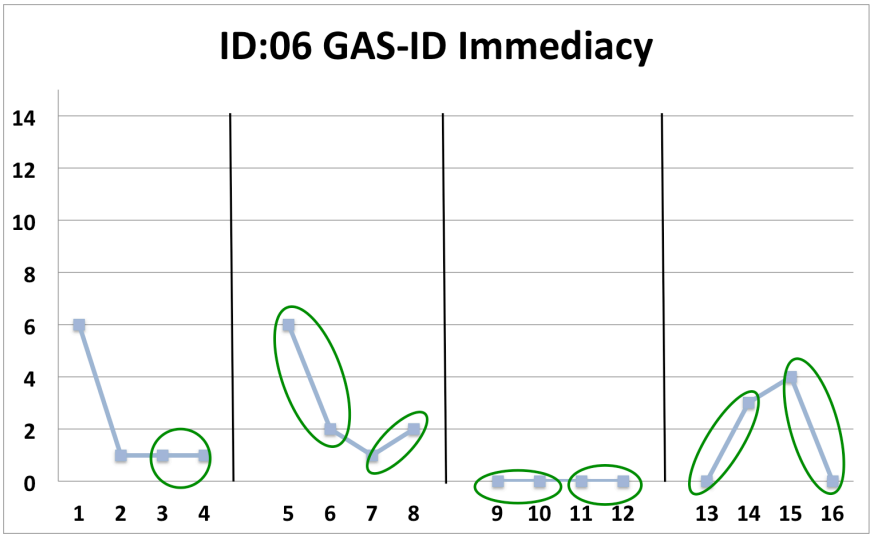
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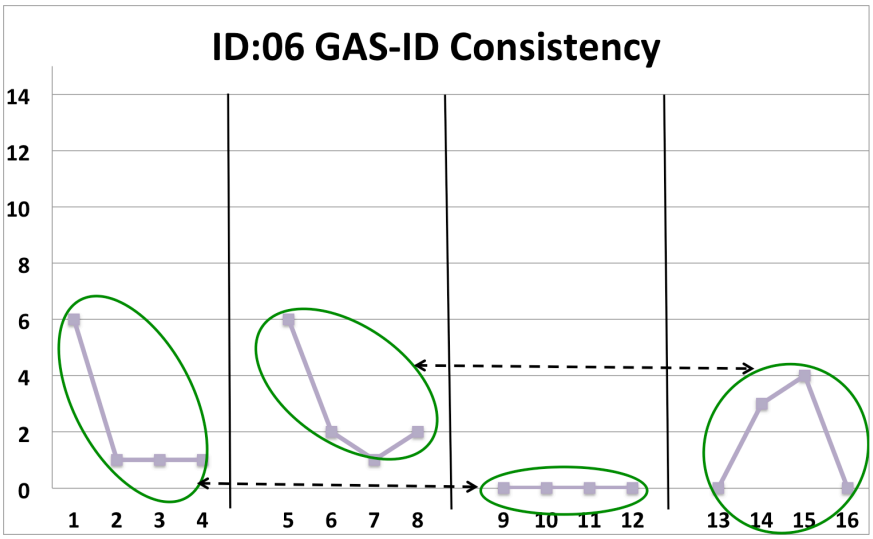
ID:06 GAS-ID Consistency
14
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10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

ID-7 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	5	8	9
2	3	6	3
3	3	6	4
4	2	4	3
5	3	3	2
6	1	4	1
7	2	3	4
8	2	7	5
9	4	8	5
10	5	9	6
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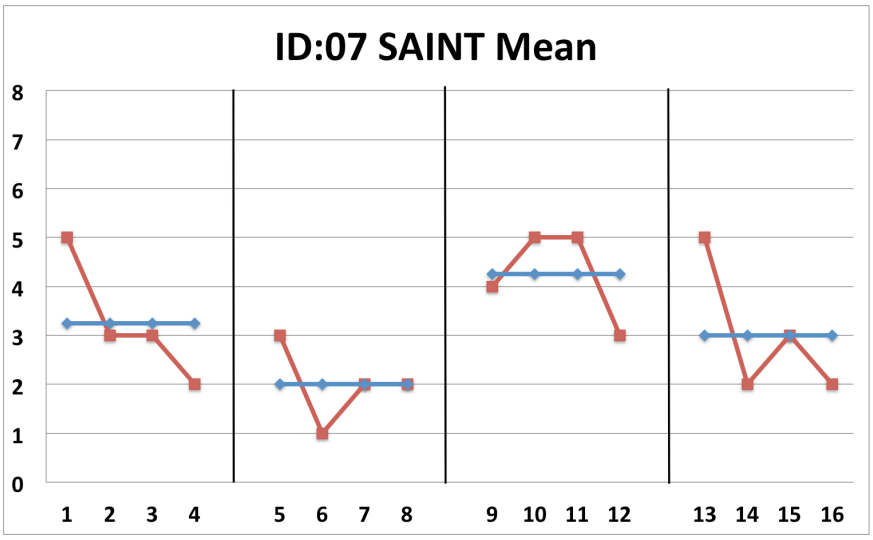
12	3	8	5
13	5	7	5
14	2	4	2
15	3	4	3
16	2	5	2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7
6
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0
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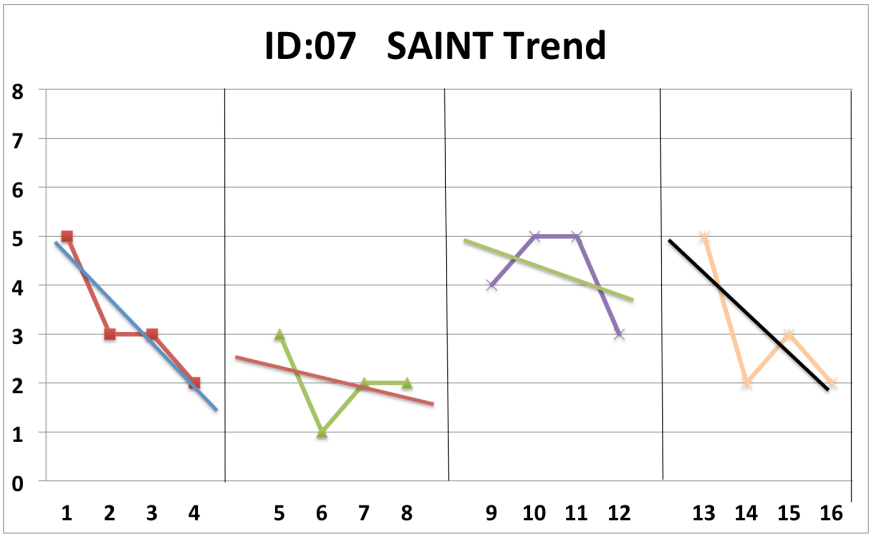
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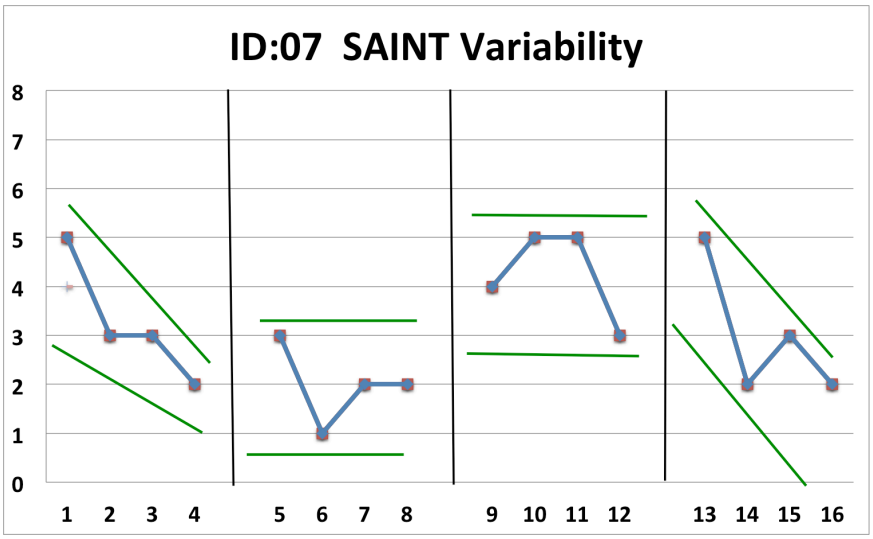
ID:07 SAINT Variability
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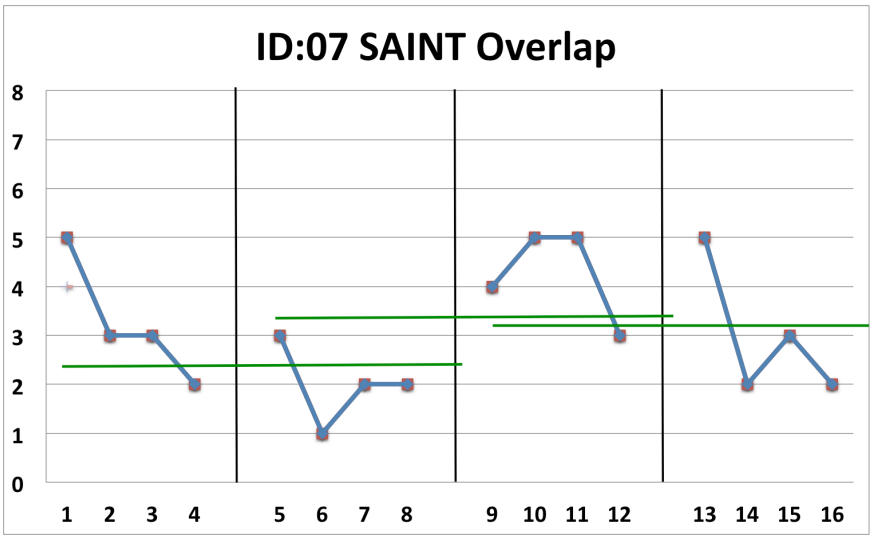
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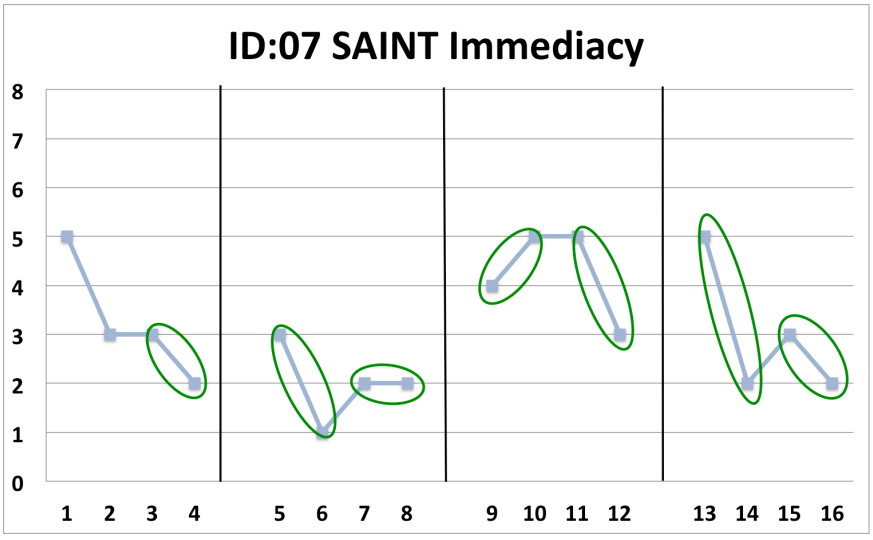
ID:07 SAINT Immediacy
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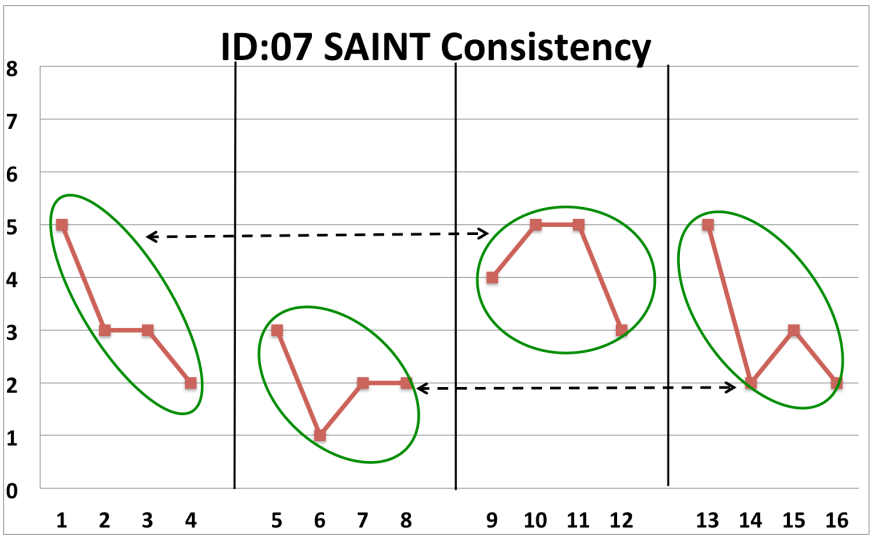
ID:07 SAINT Consistency
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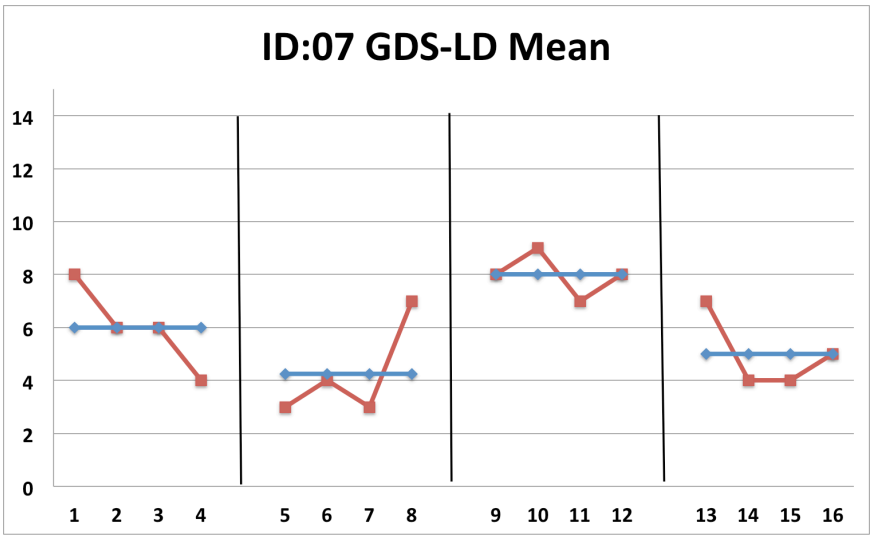
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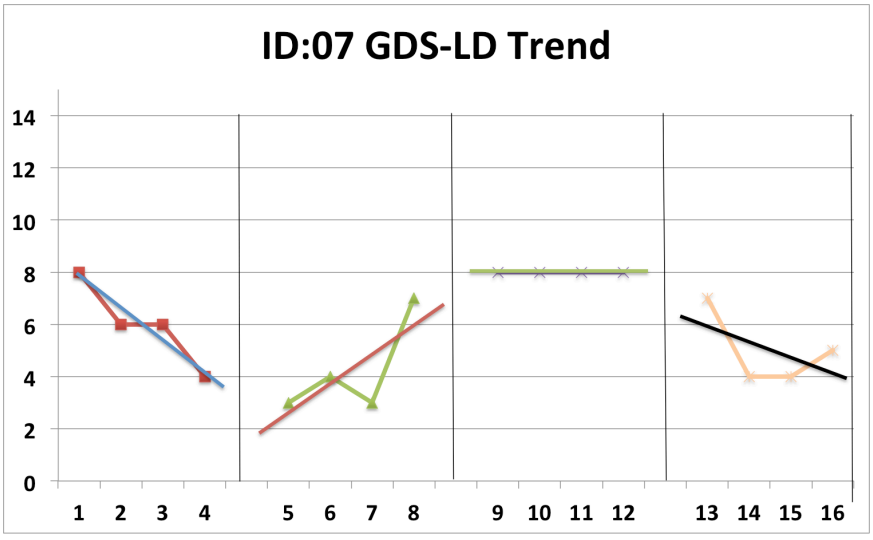
ID:07 GDS-LD Trend
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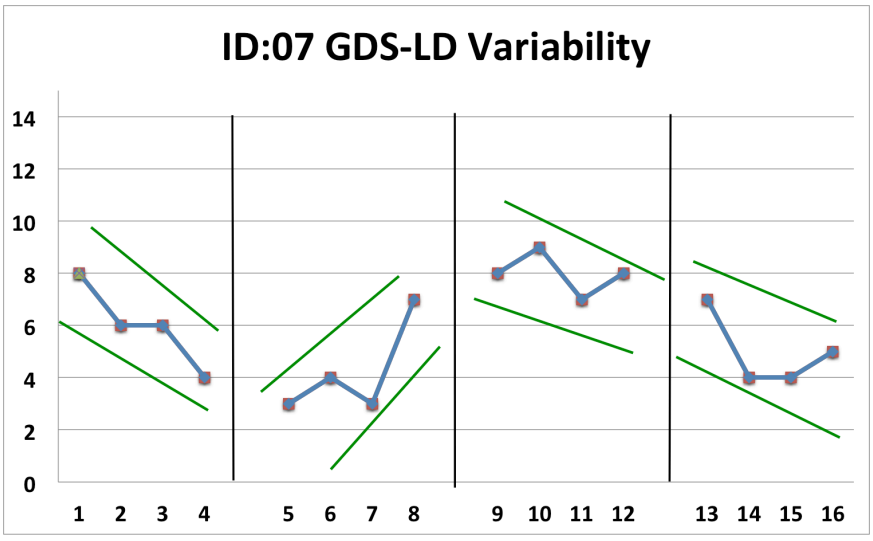
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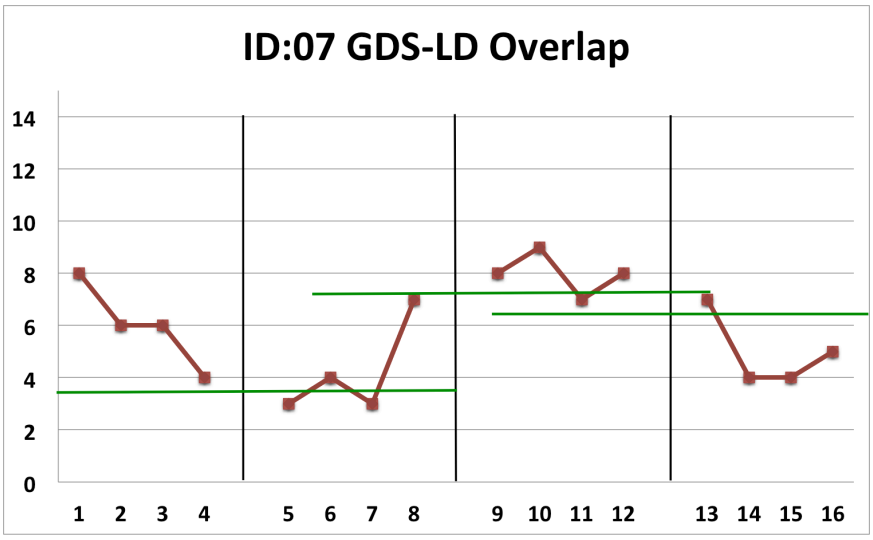
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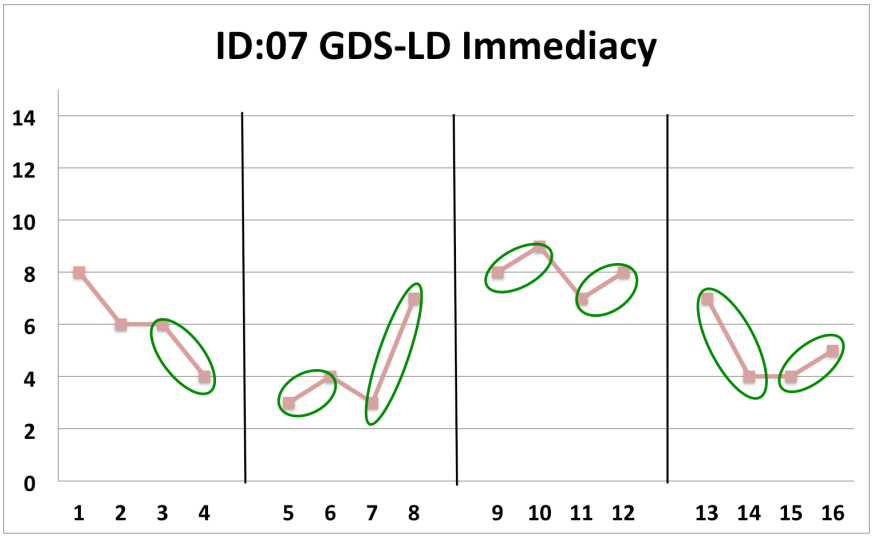
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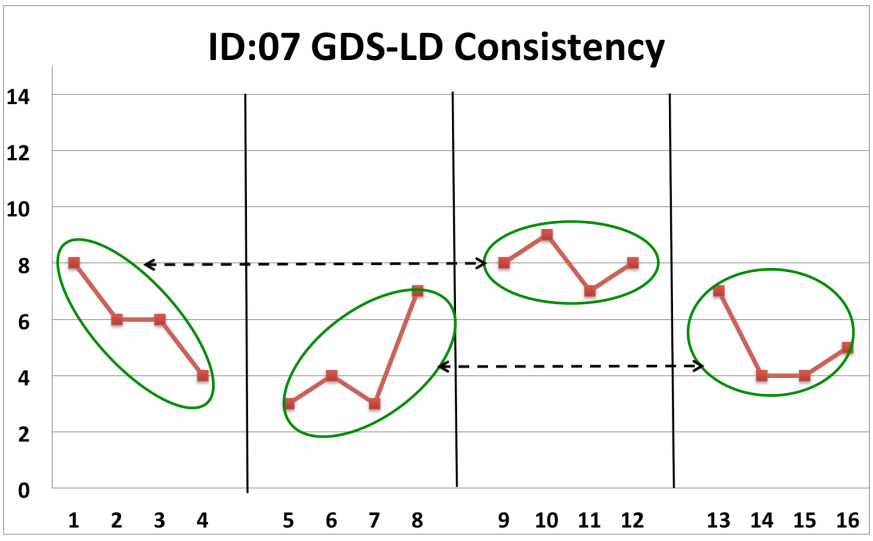
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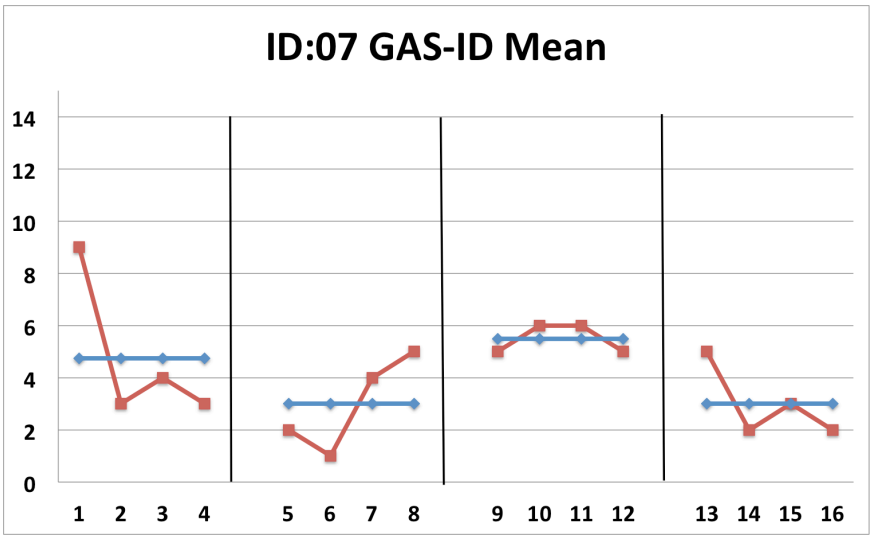
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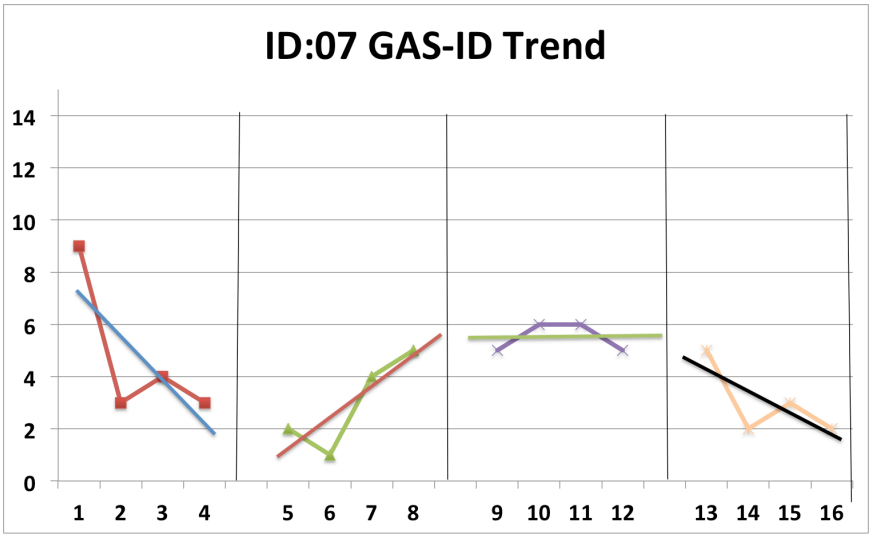
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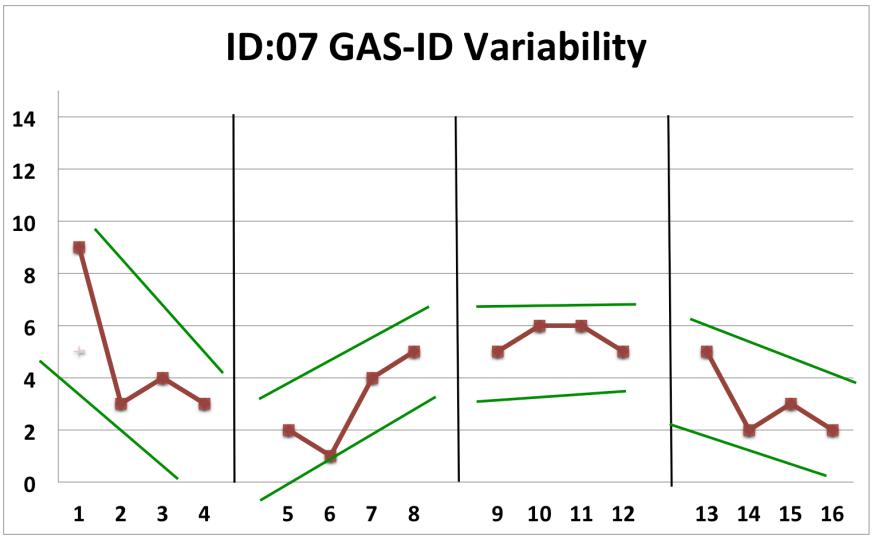
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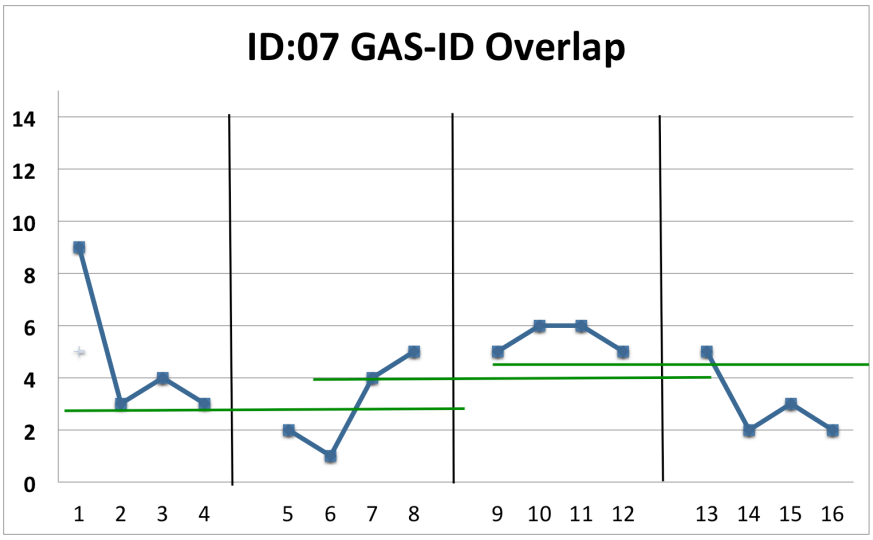
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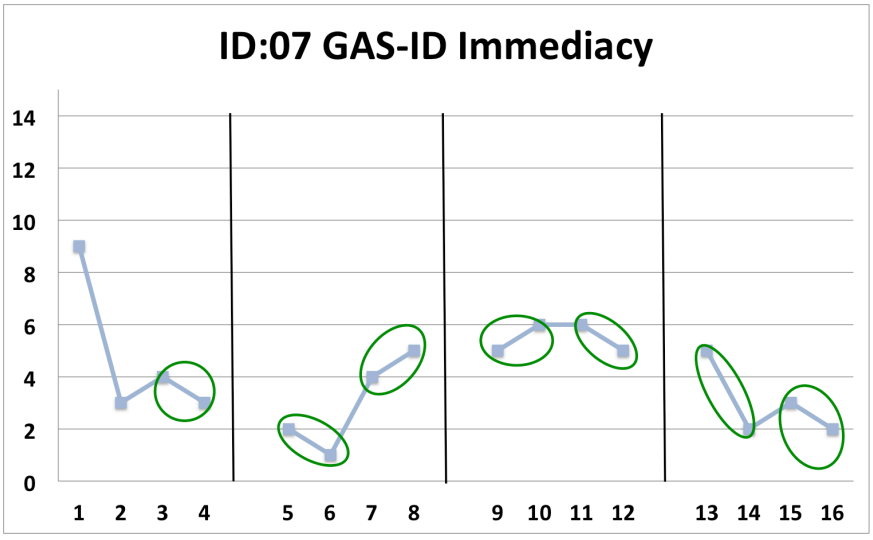
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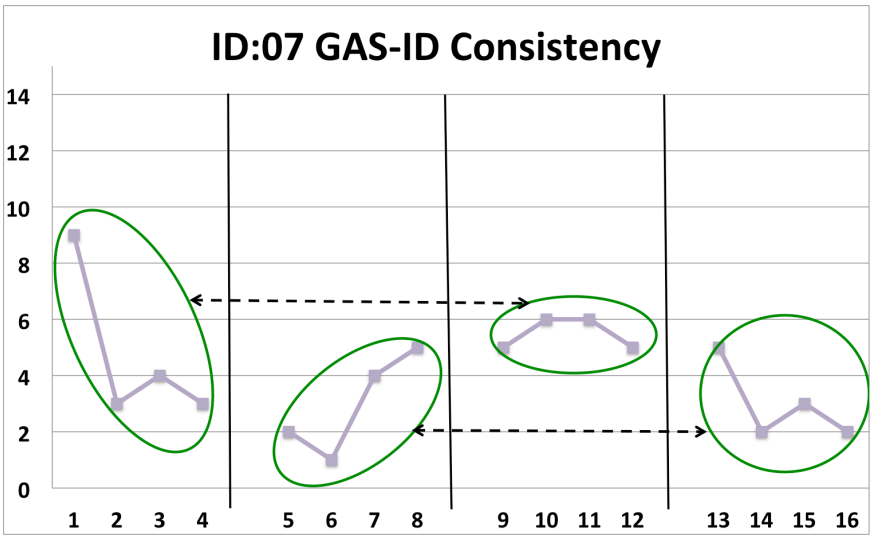
ID:07 GAS-ID Consistency
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

ID-8 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	1	3	3
2	2	4	4
3	2	5	1
4	2	3	2
5	0	2	2
6	1	1	3
7	2	2	2
8	2	2	2
9	1	4	2
10	2	5	2
11	2	2	2
12	2	2	1
13	1	2	2
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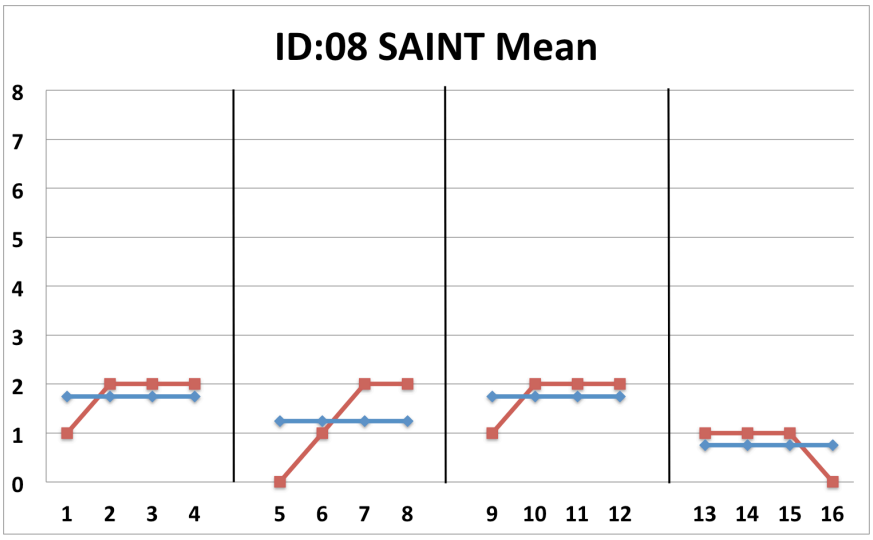
15	1	2	4
16	0	1	1


ID:08 SAINT Mean
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3
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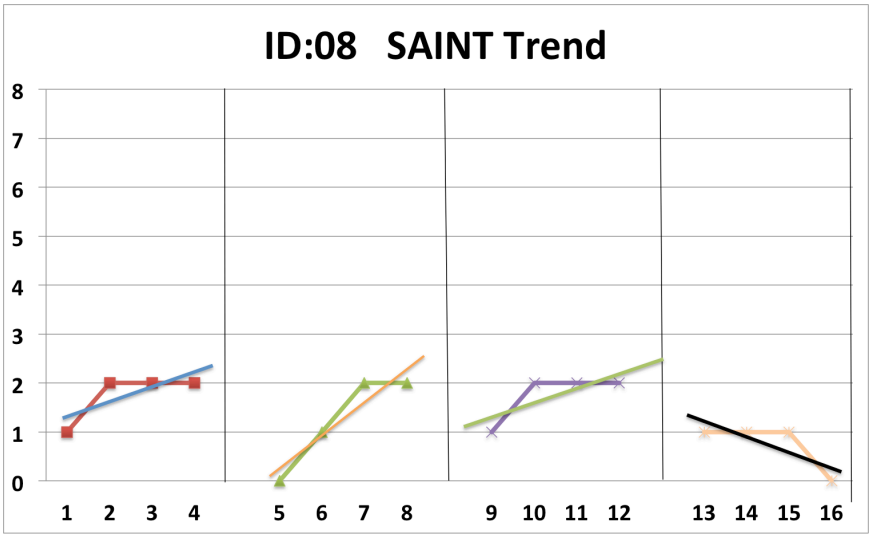
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2
1
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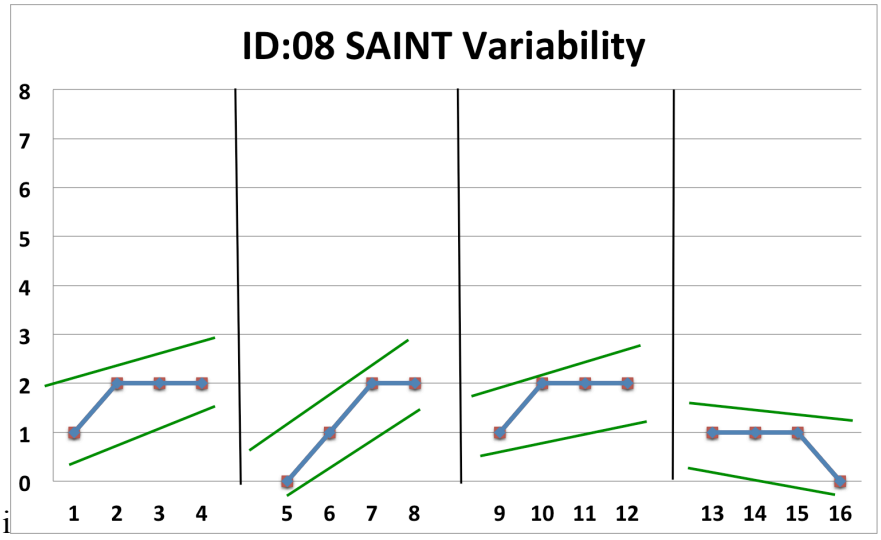
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:08 SAINT Variability
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5
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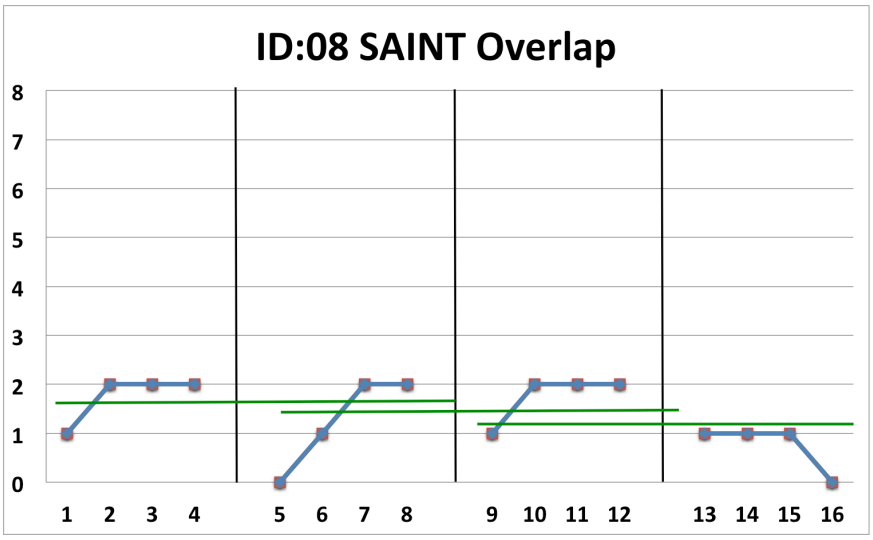
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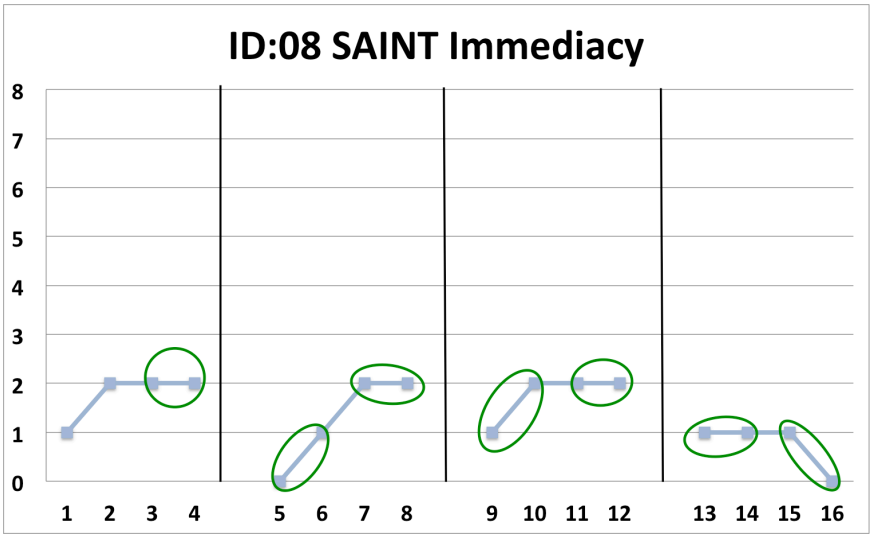
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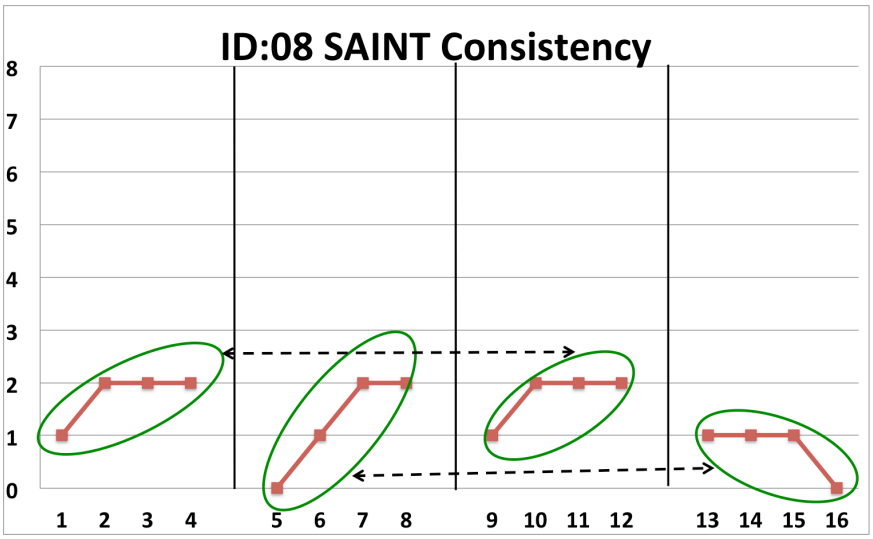
ID:08 SAINT Consistency
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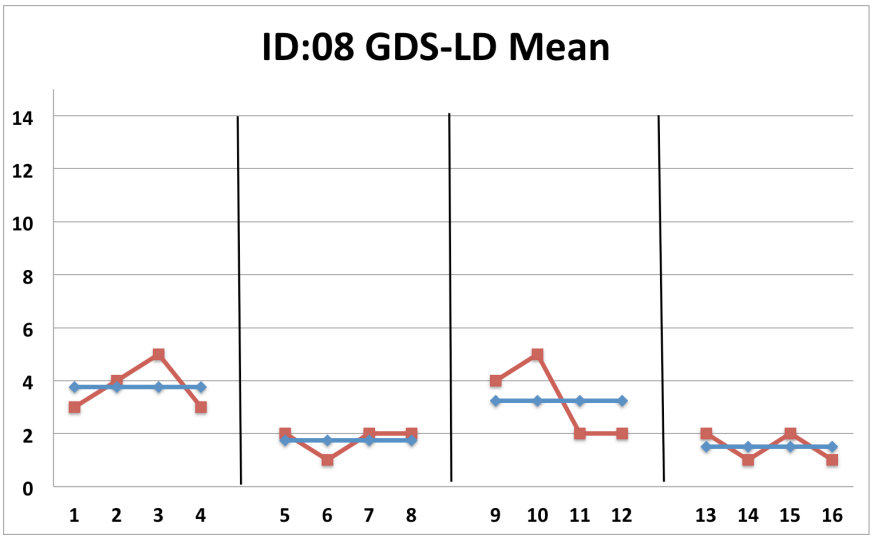
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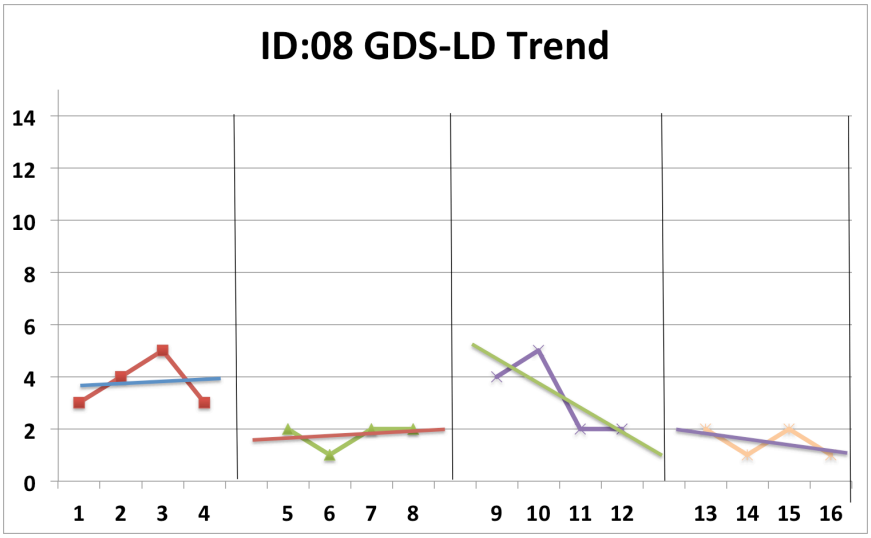
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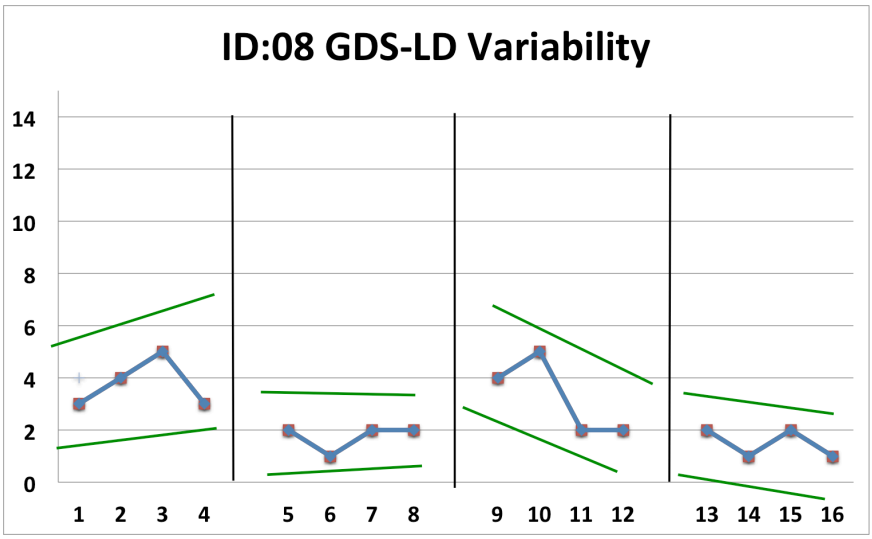
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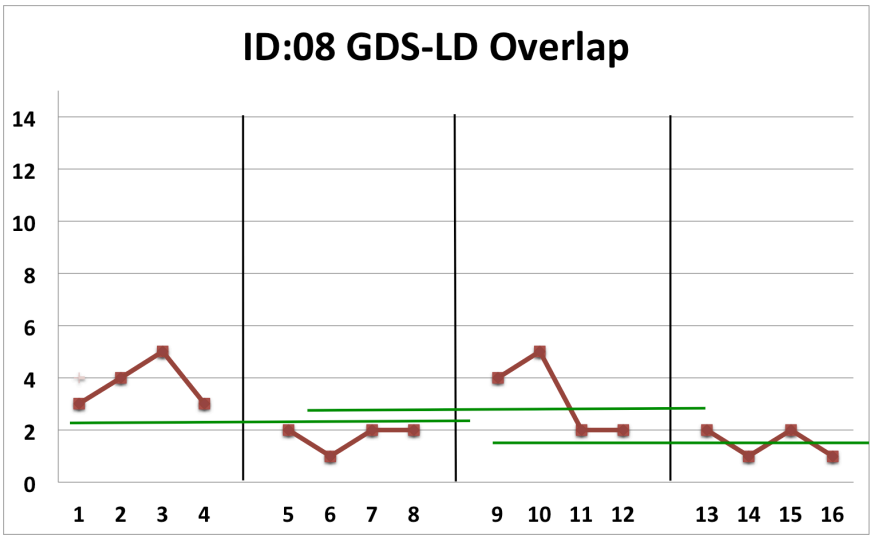
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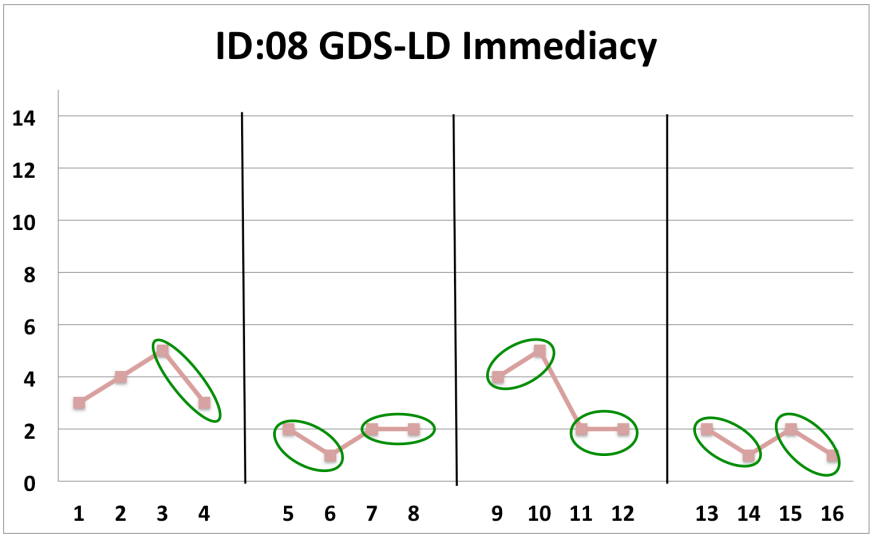
ID:08 GDS-LD Immediacy
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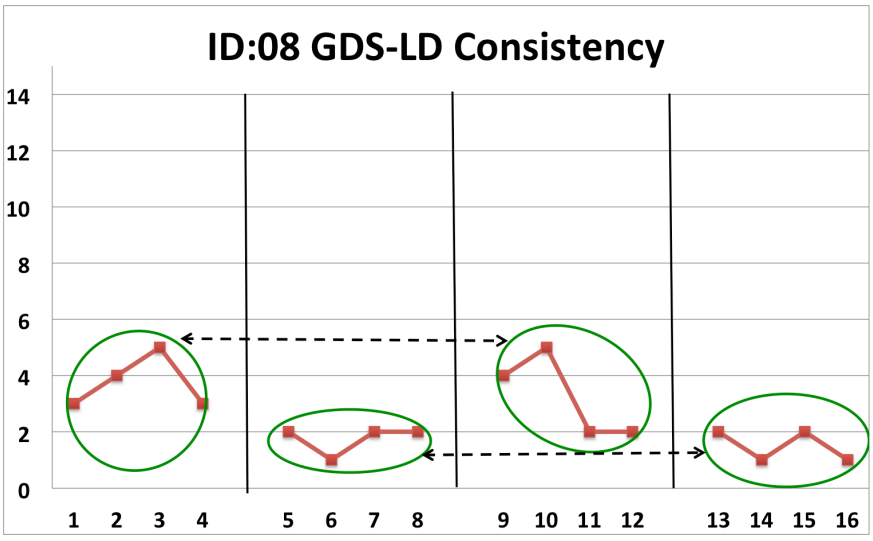
ID:08 GDS-LD Consistency
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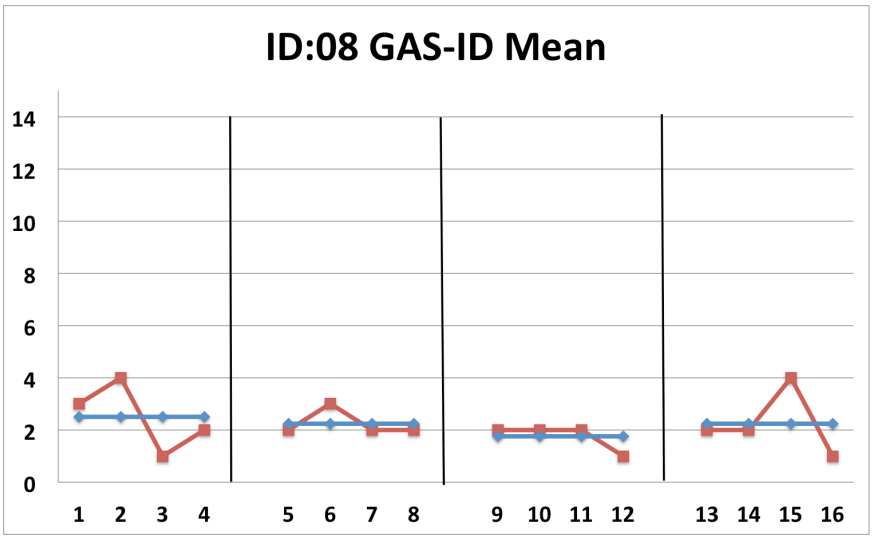
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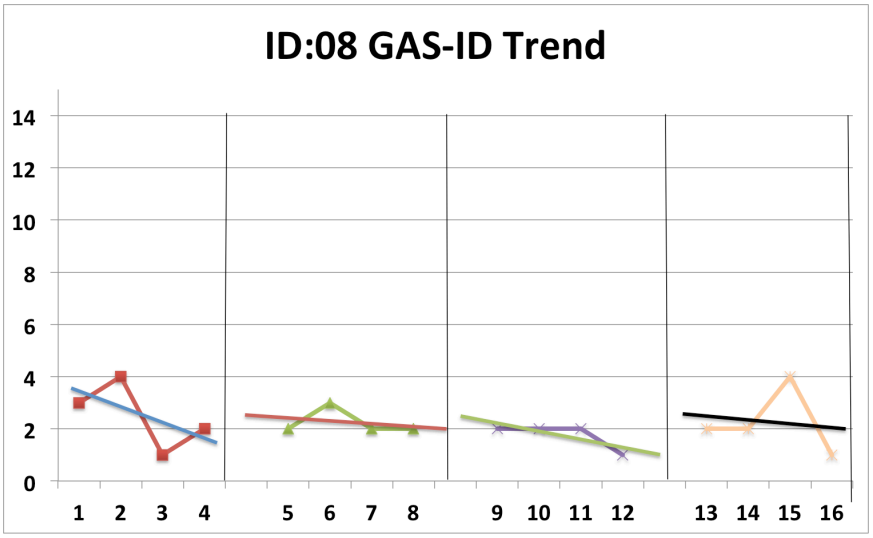
ID:08 GAS-ID Trend
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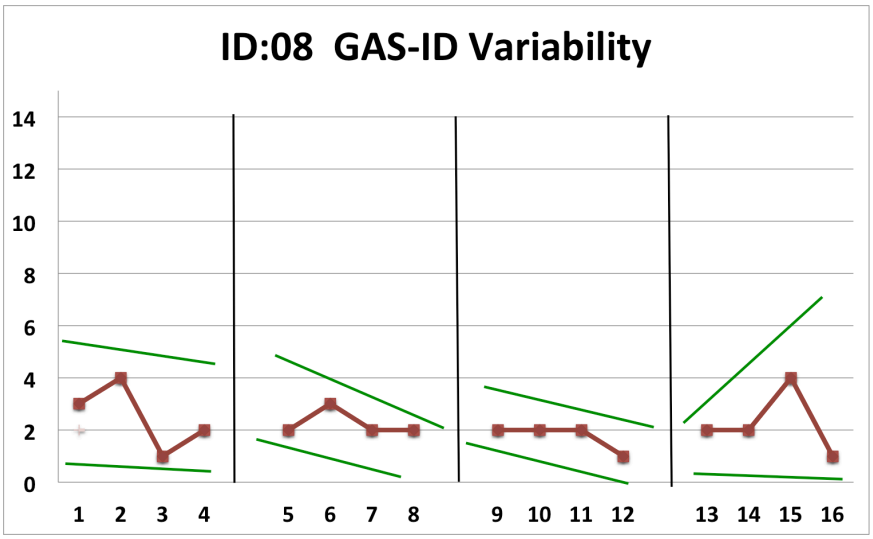
ID:08 GAS-ID Variability
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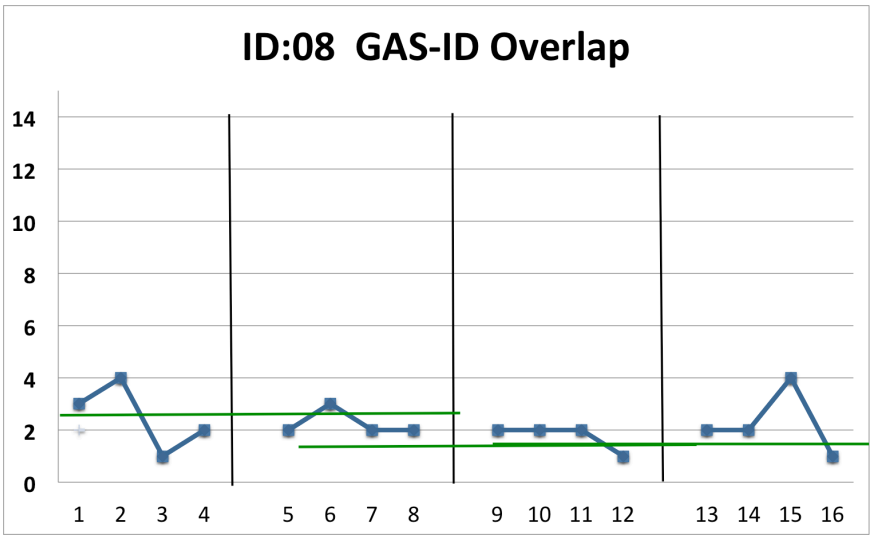
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:08 GAS-ID Overlap
14
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2
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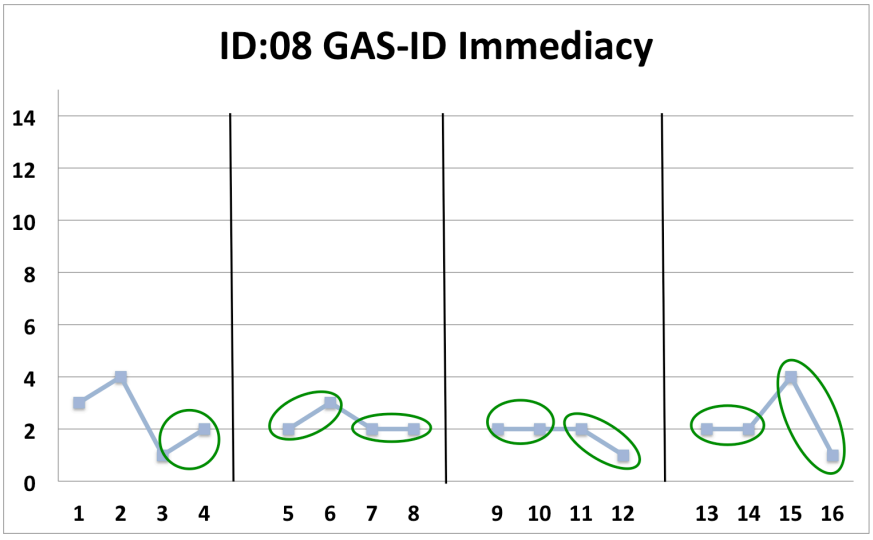
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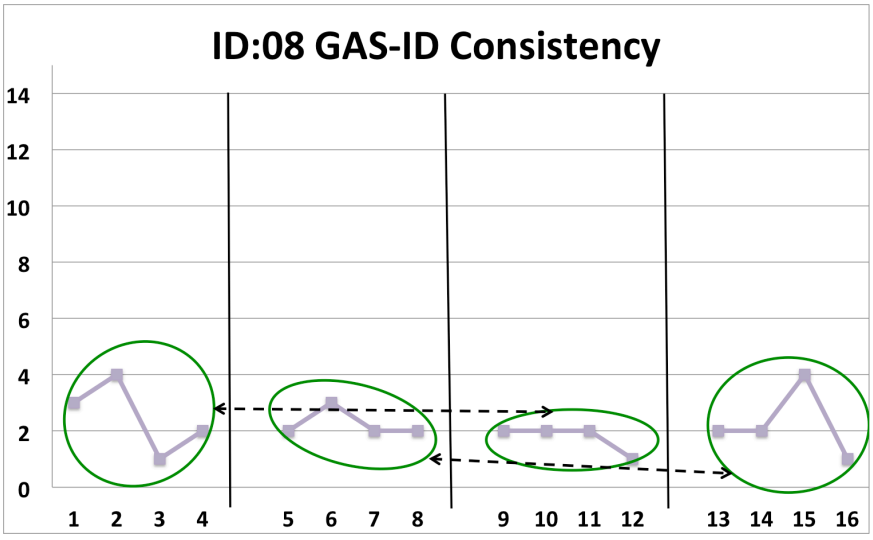
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ID-9 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	2	10	18
2	**3.3**	**14.7**	**15**
3	4	17	18
4	4	17	9
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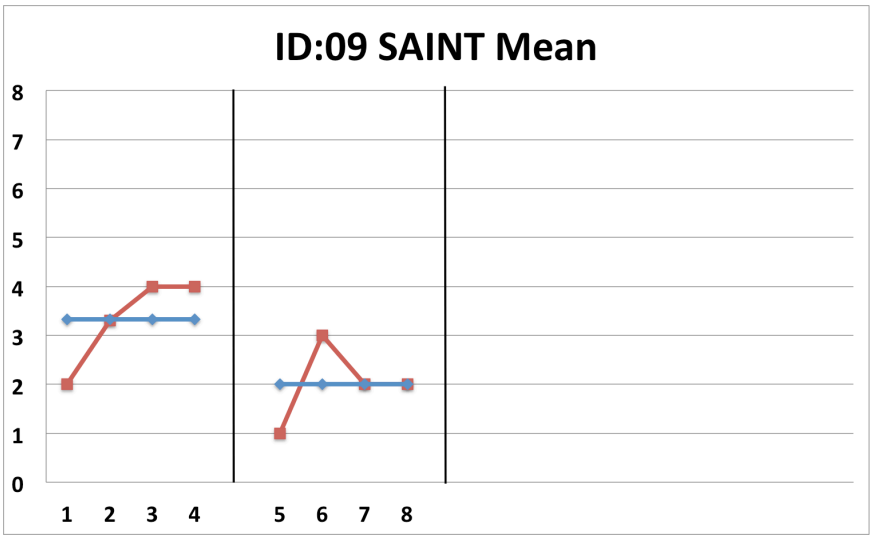
6	3	6	12
7	**2**	**8**	**15.5**
8	**2**	**8**	**15.5**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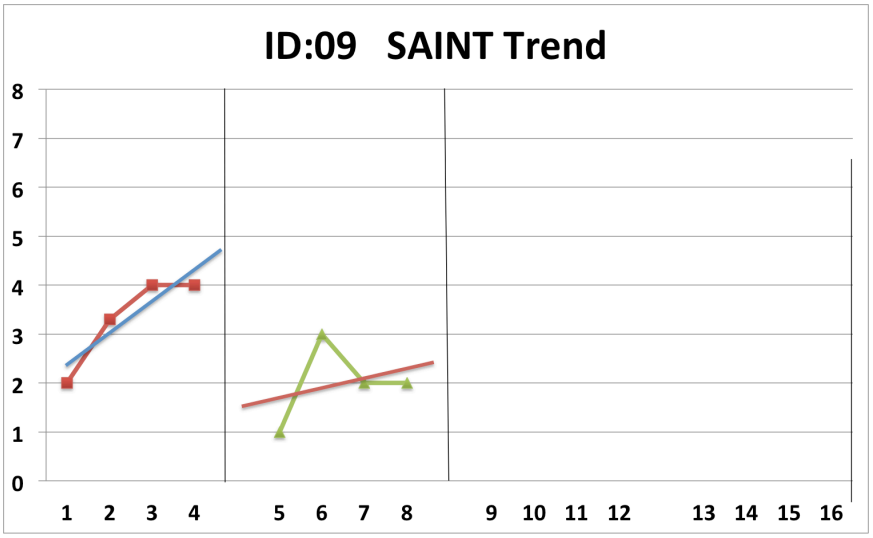
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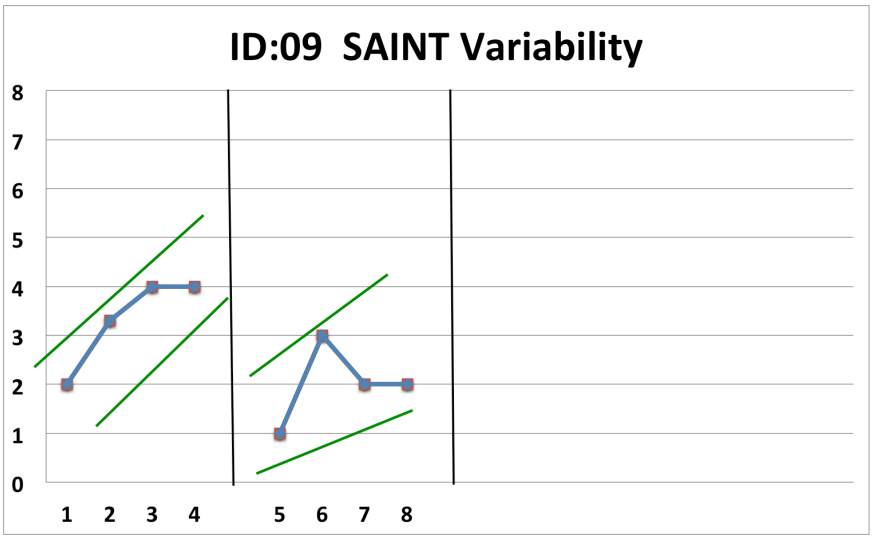
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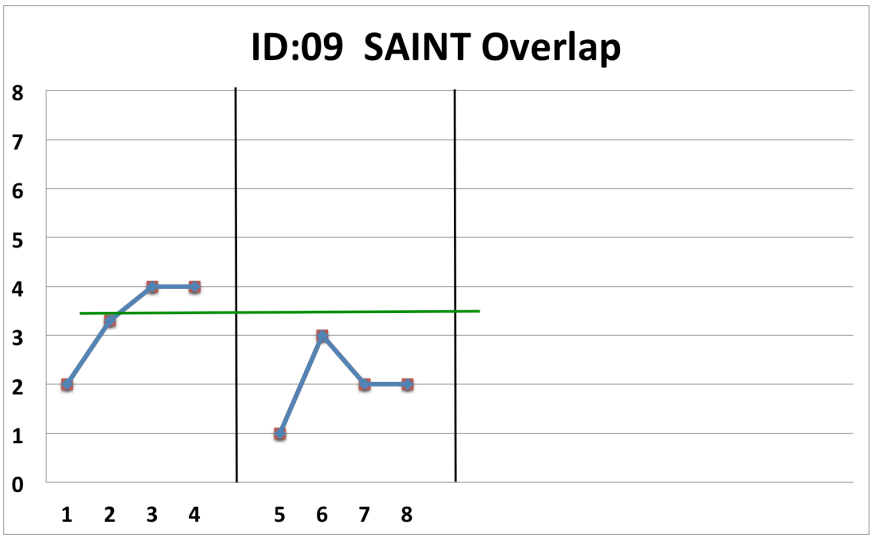
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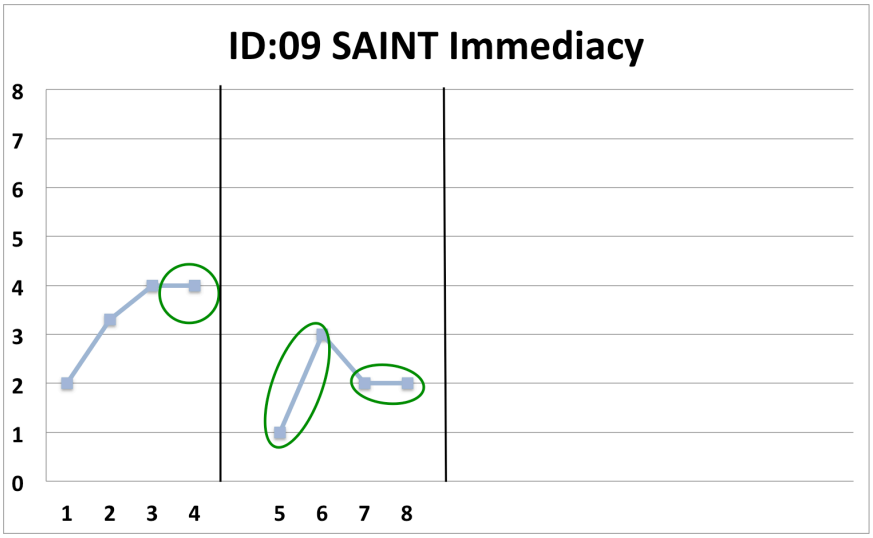
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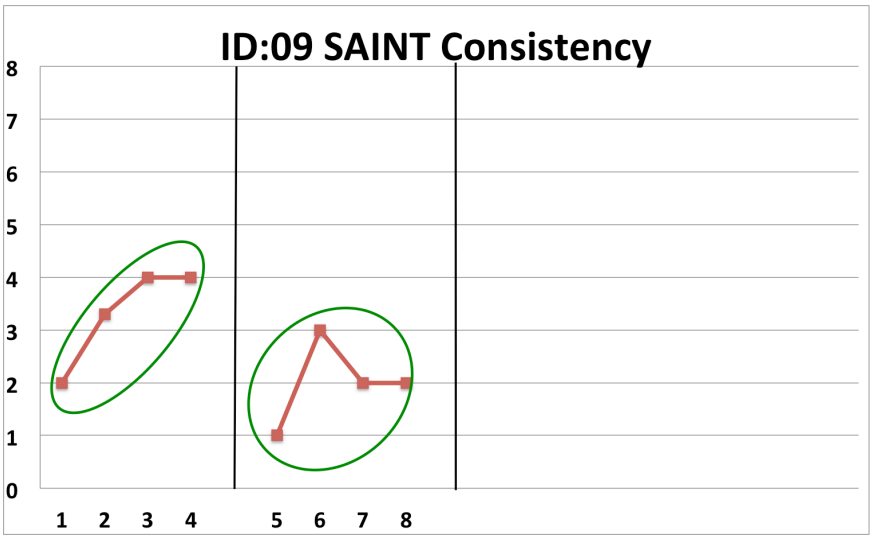
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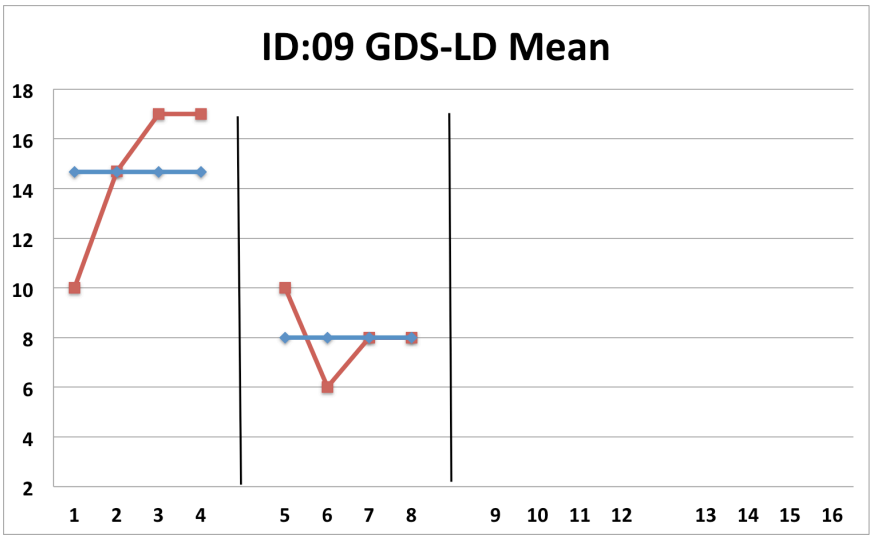
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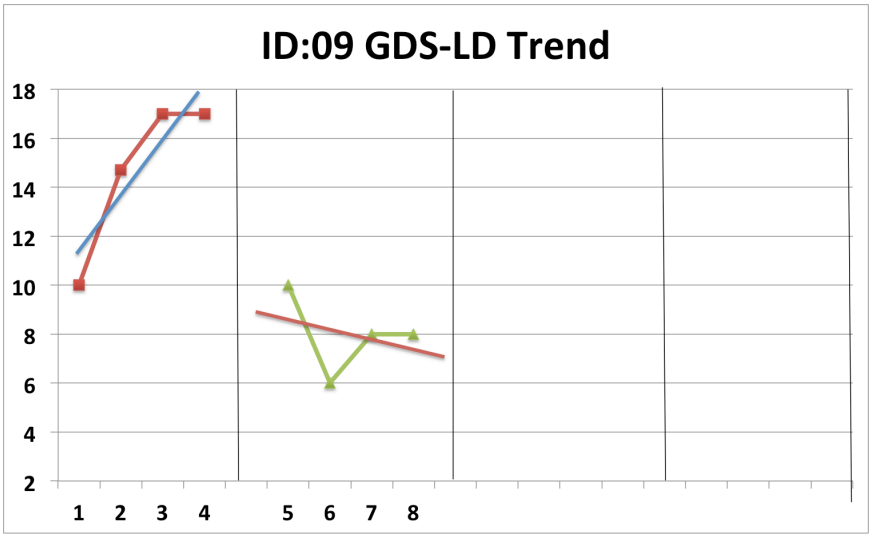
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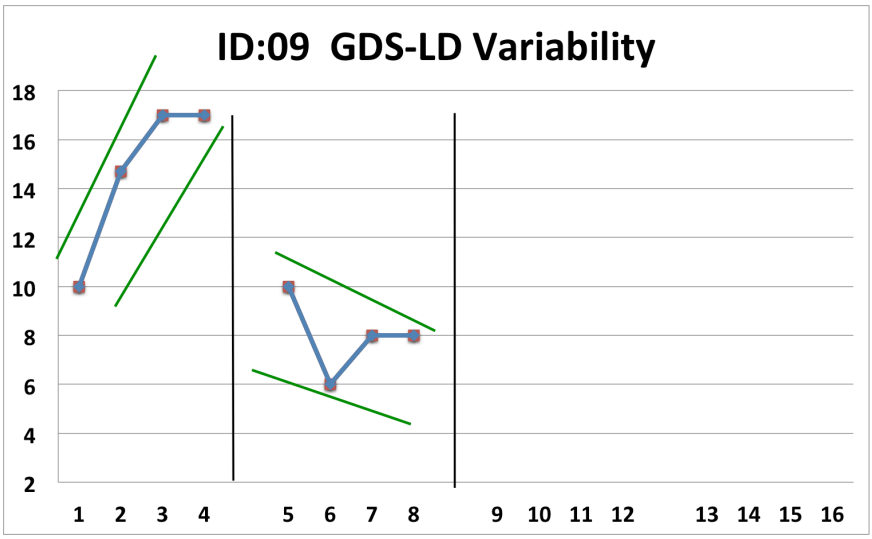
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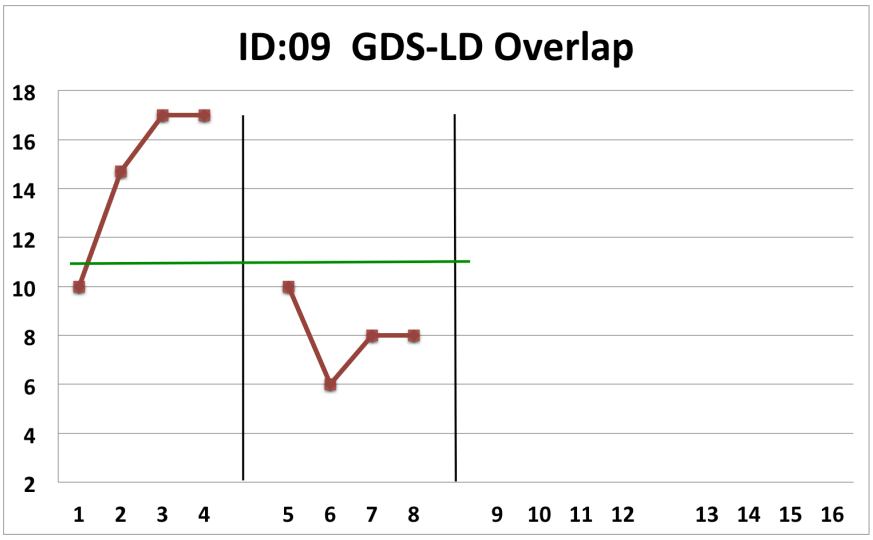
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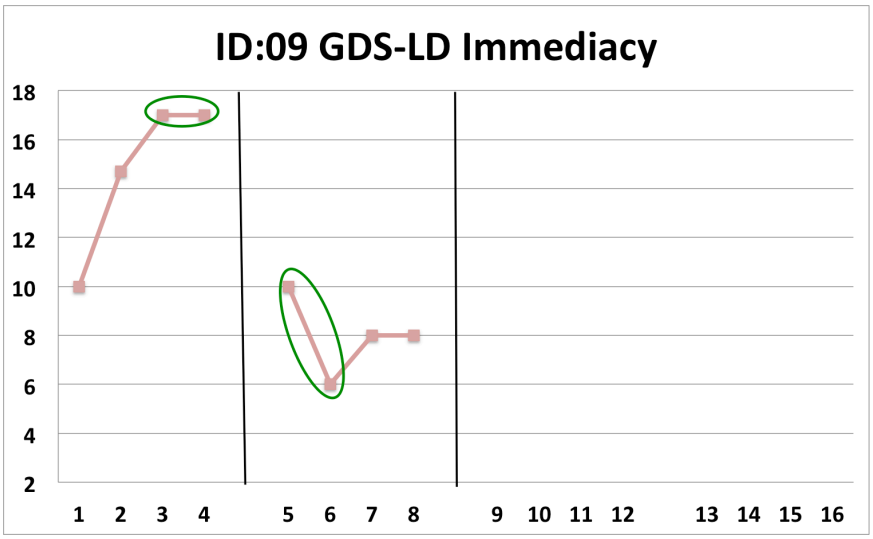
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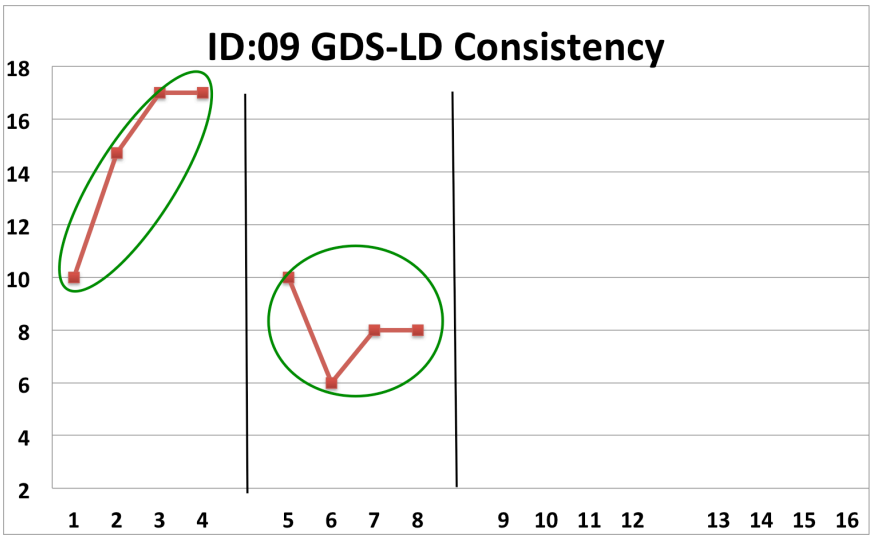
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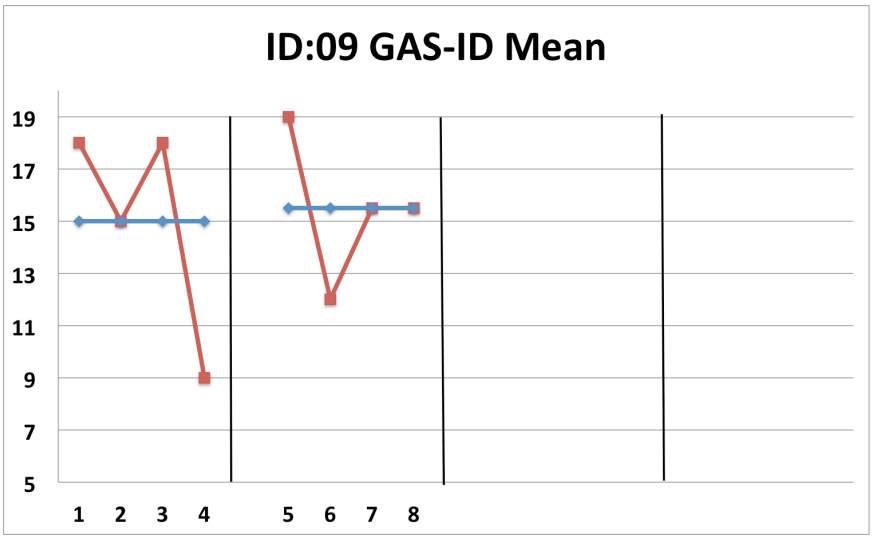
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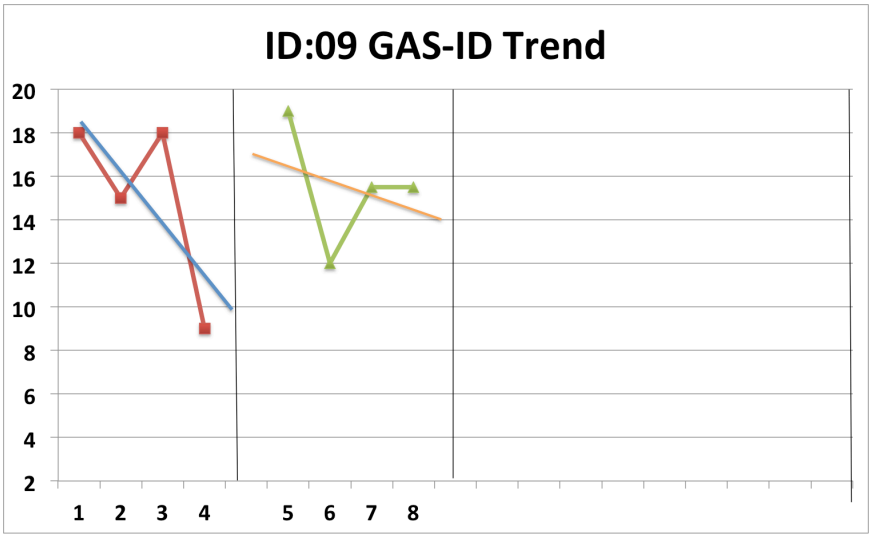
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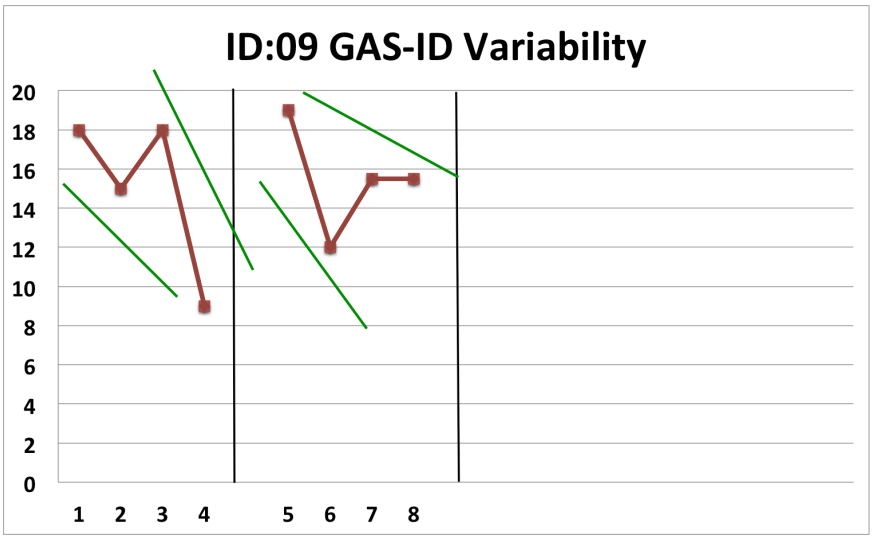
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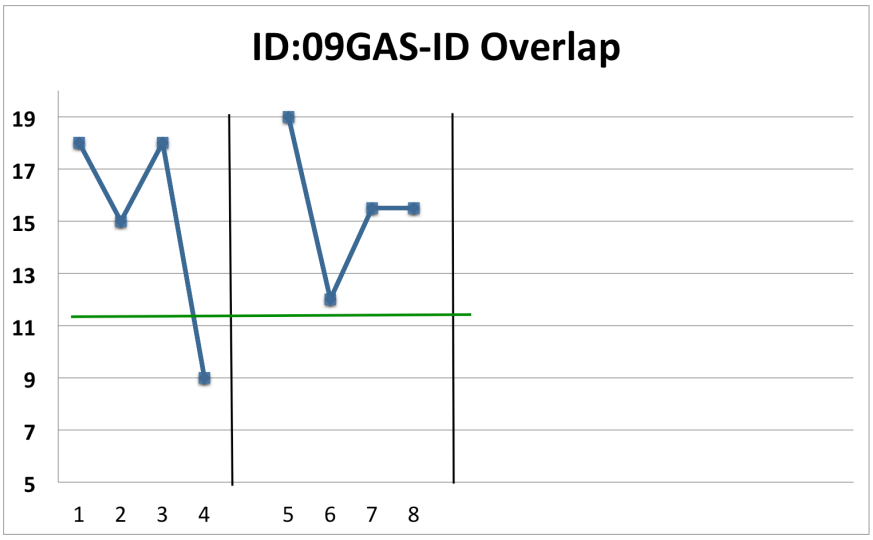
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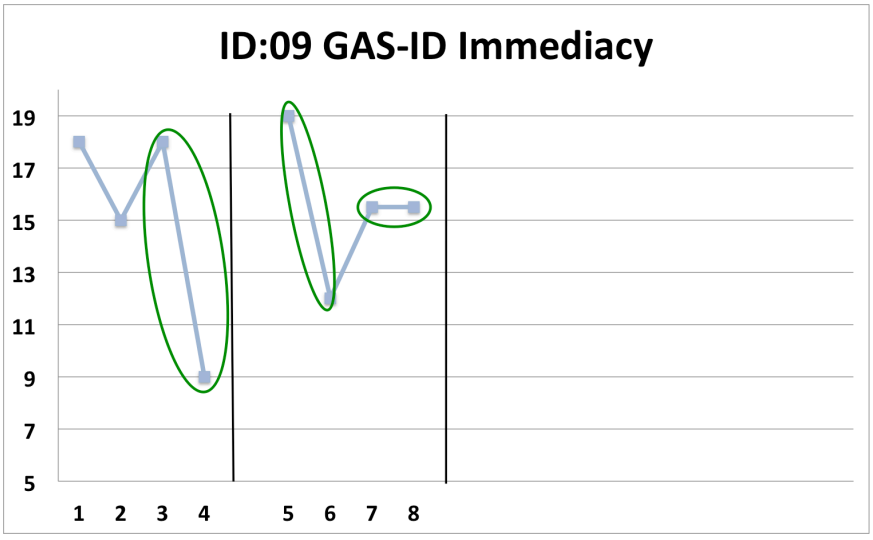
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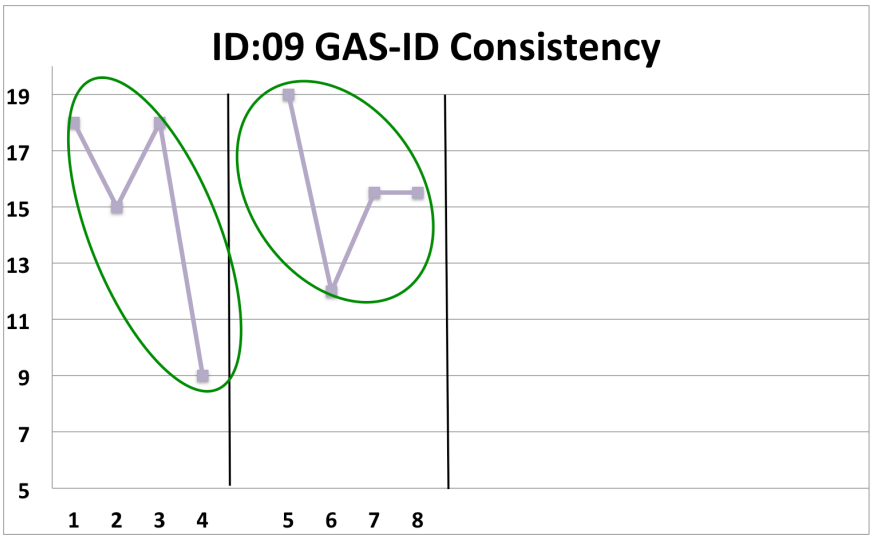
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1 2 3 4 5 6 7 8

week	SAINT	GDS-LD	GAS-ID
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5	6	16	11
6	7	12	7
7	8	23	14
8	8	15	12
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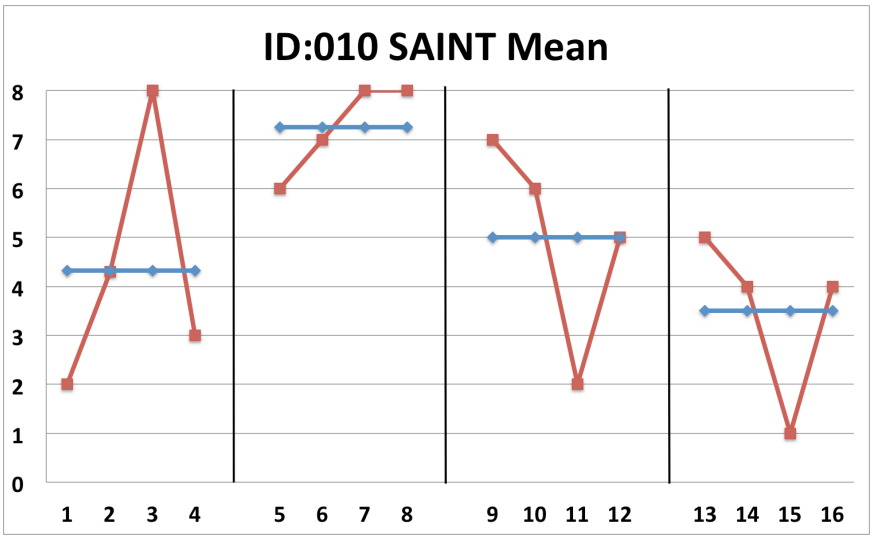
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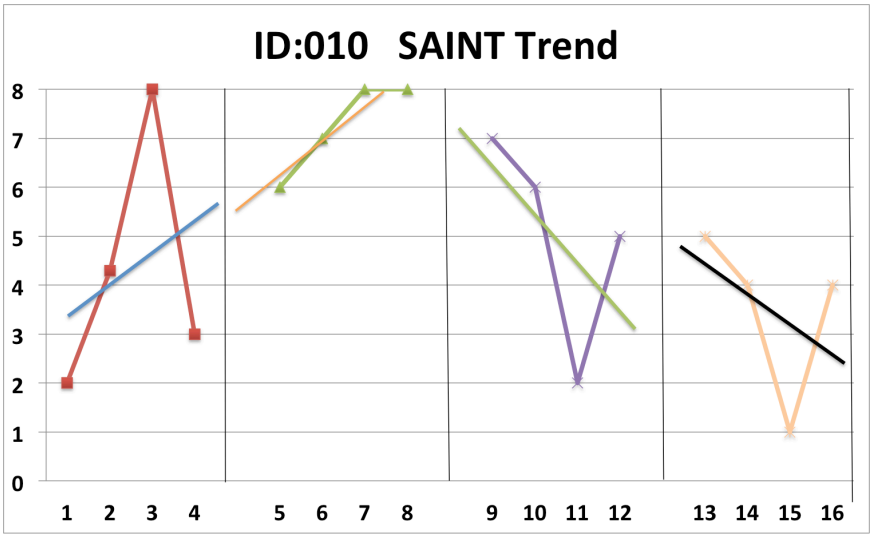
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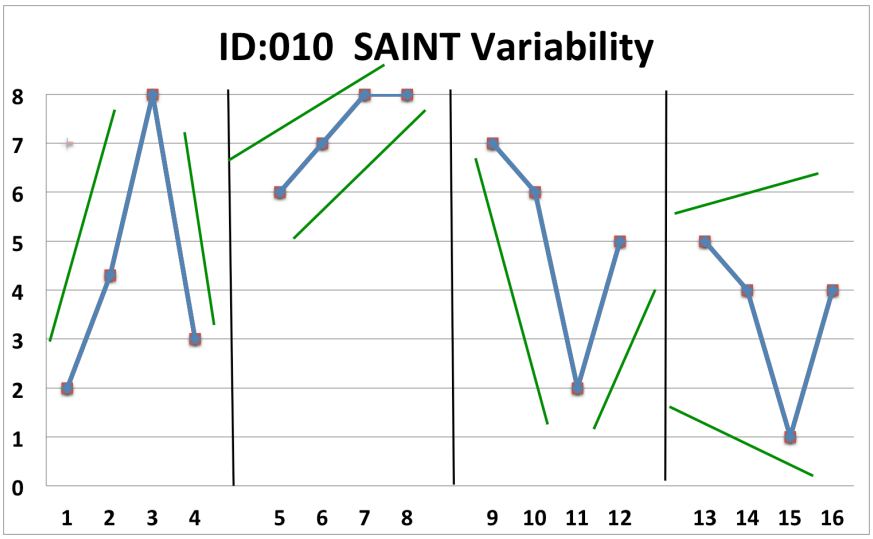
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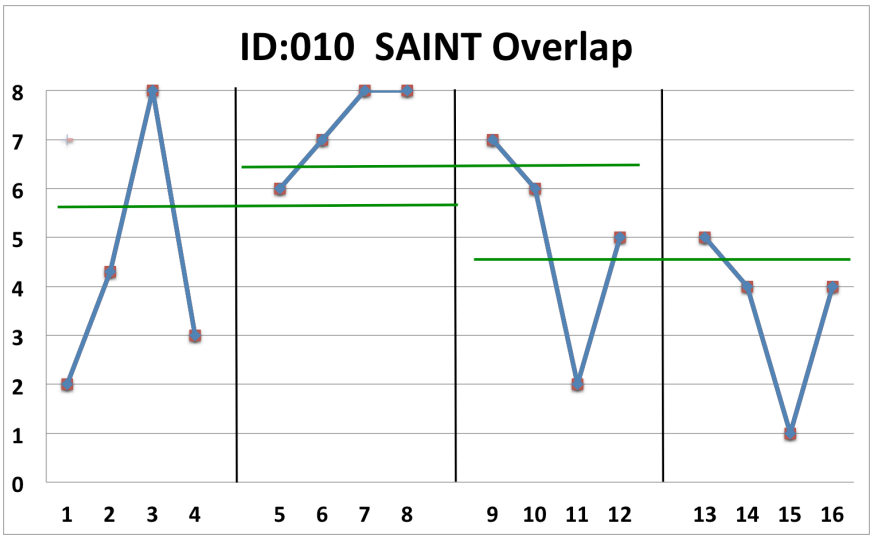
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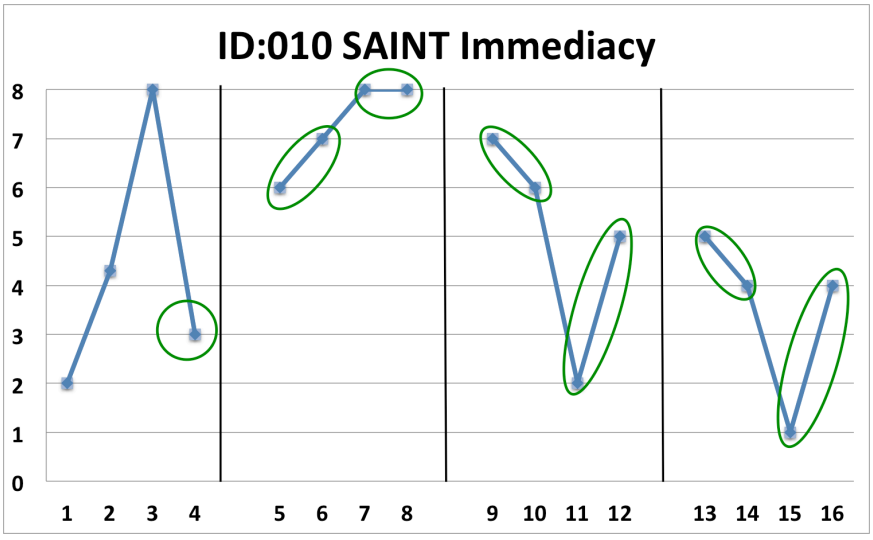
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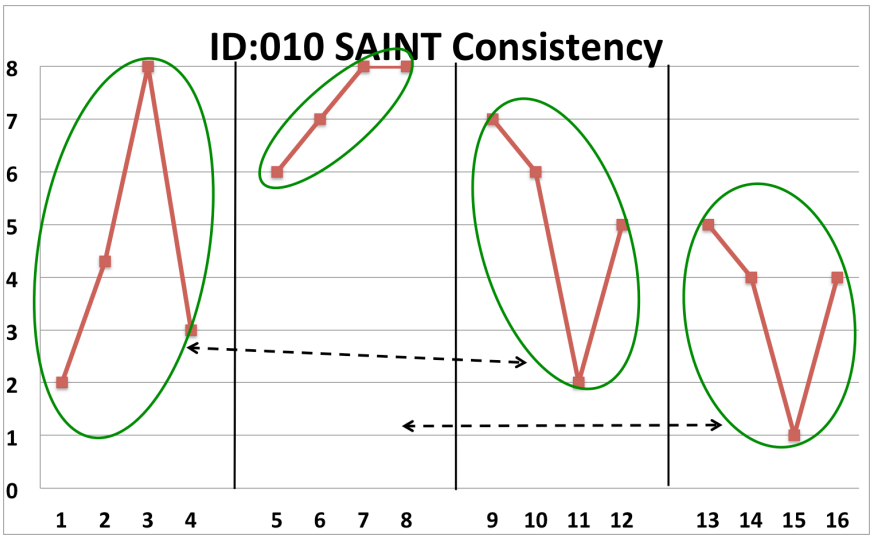
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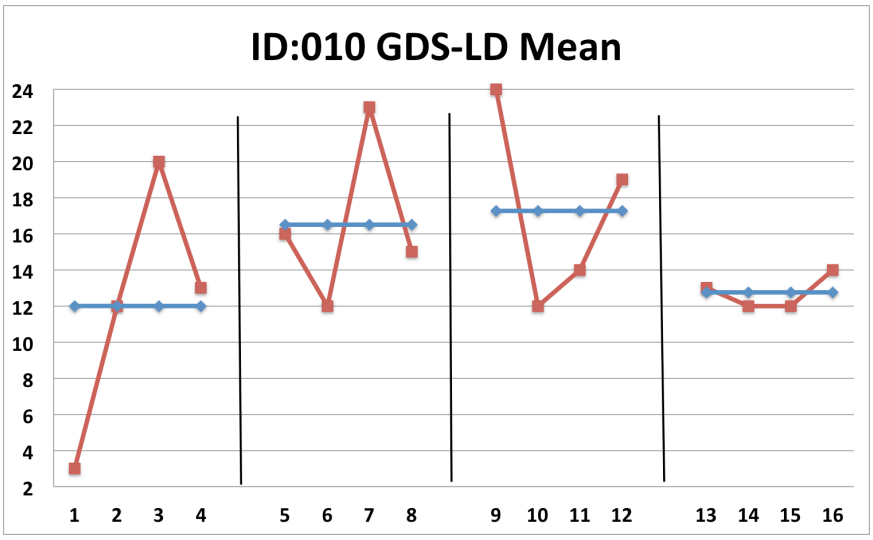
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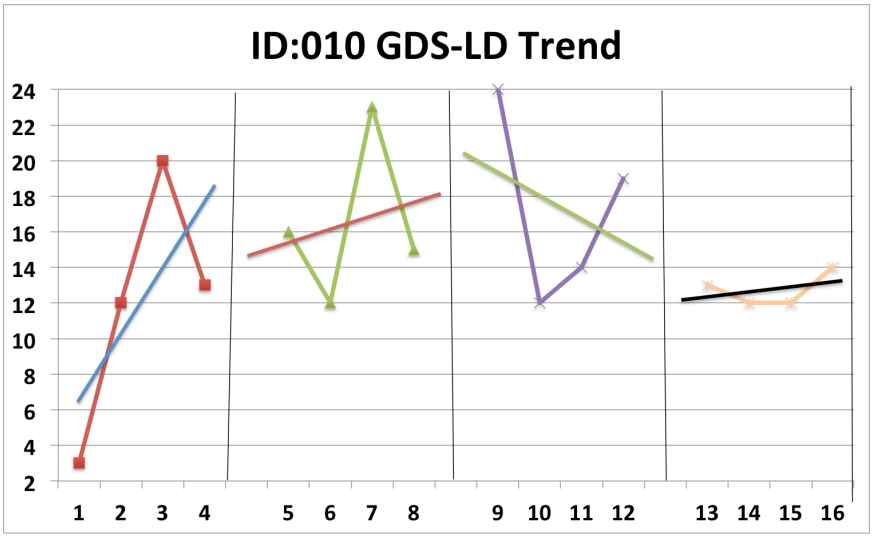
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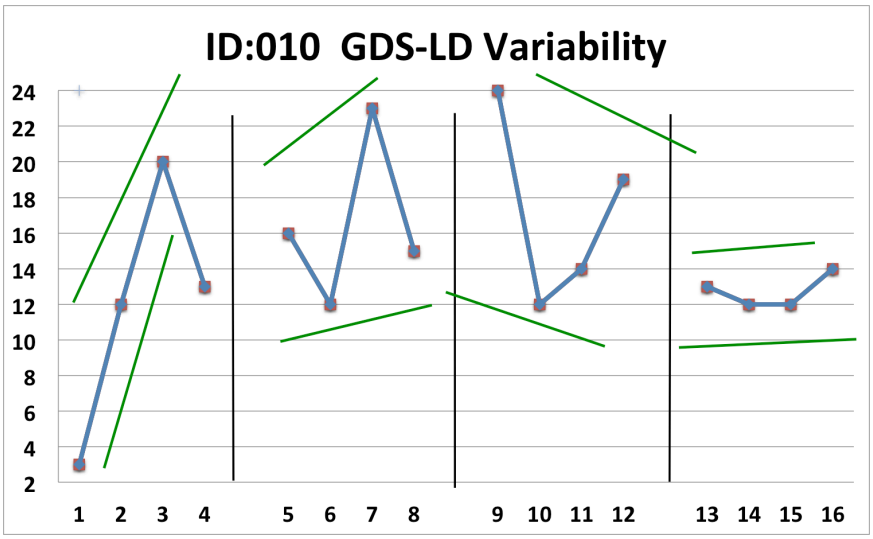
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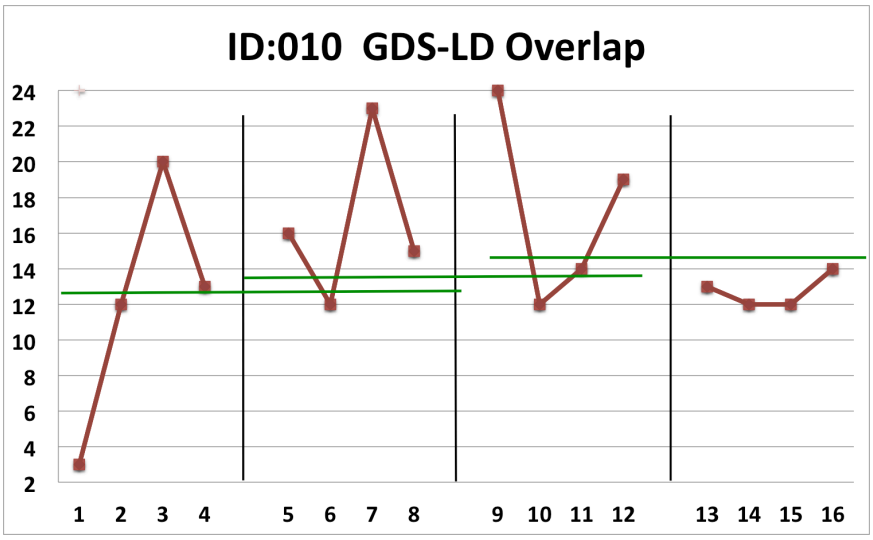
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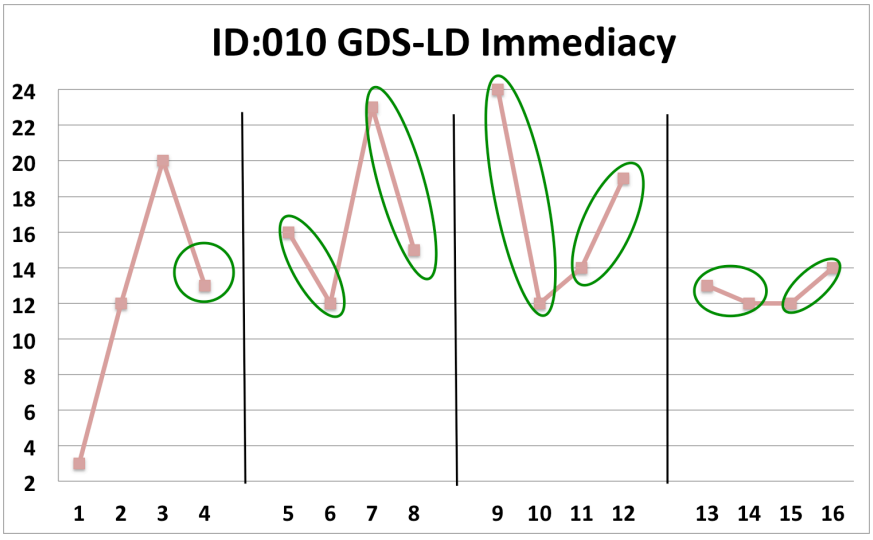
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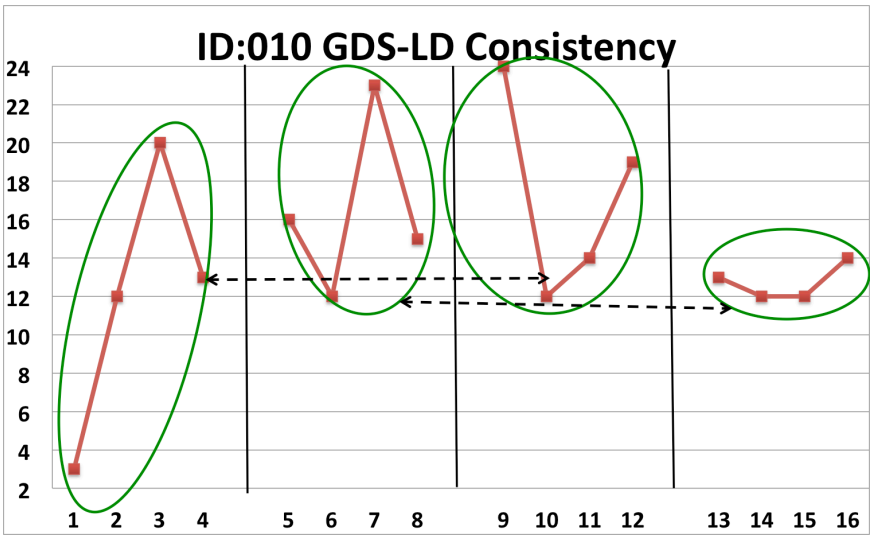
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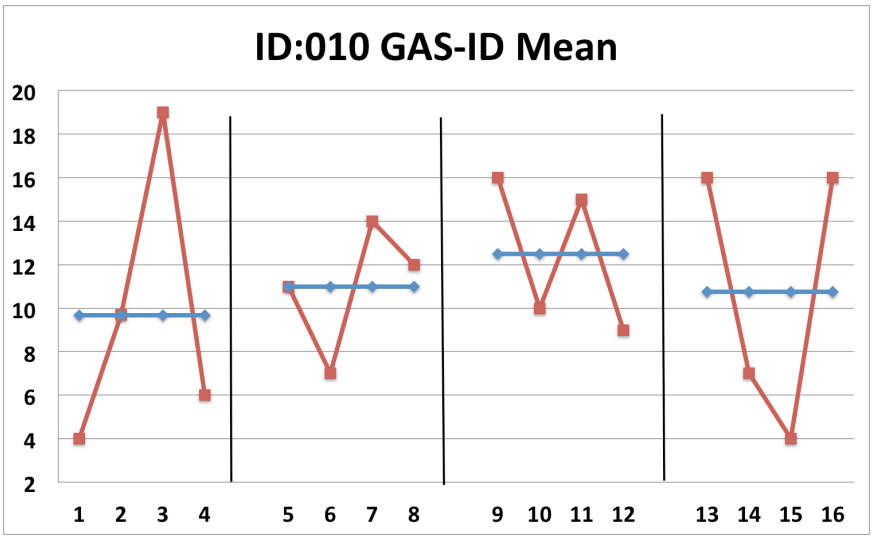
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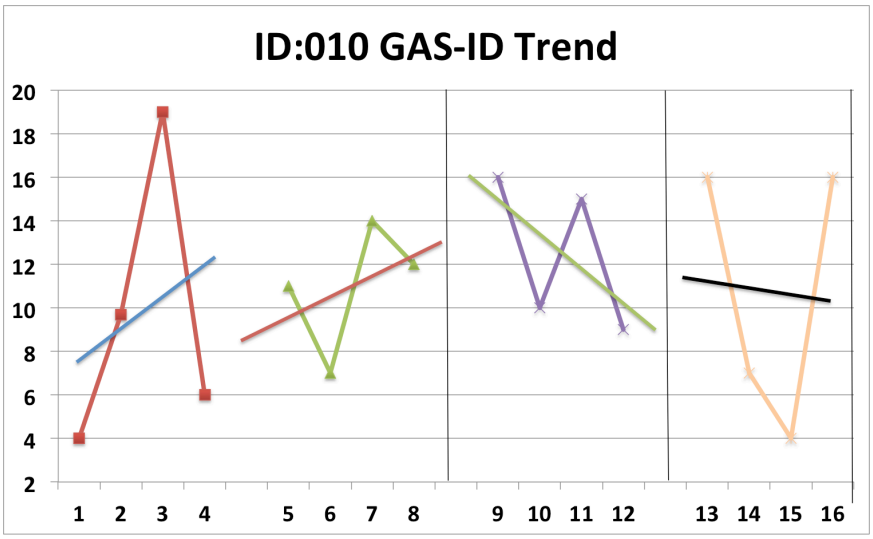
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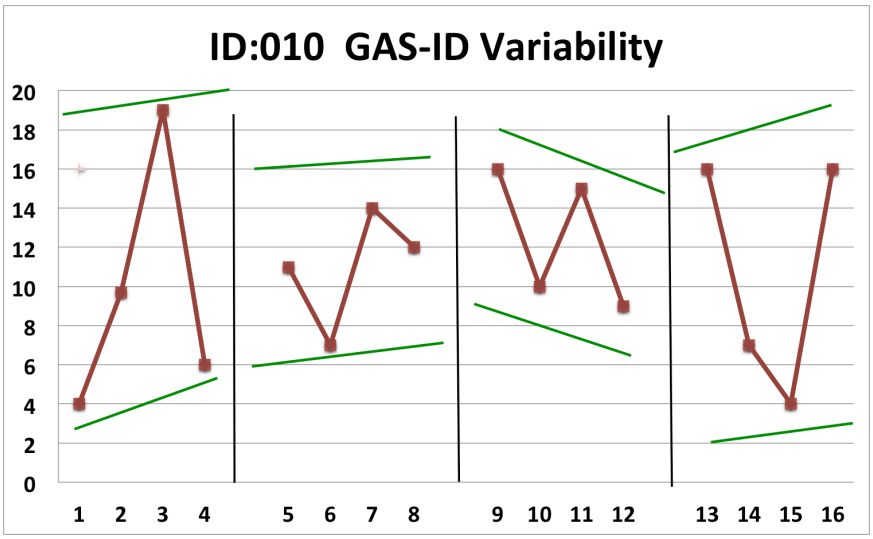
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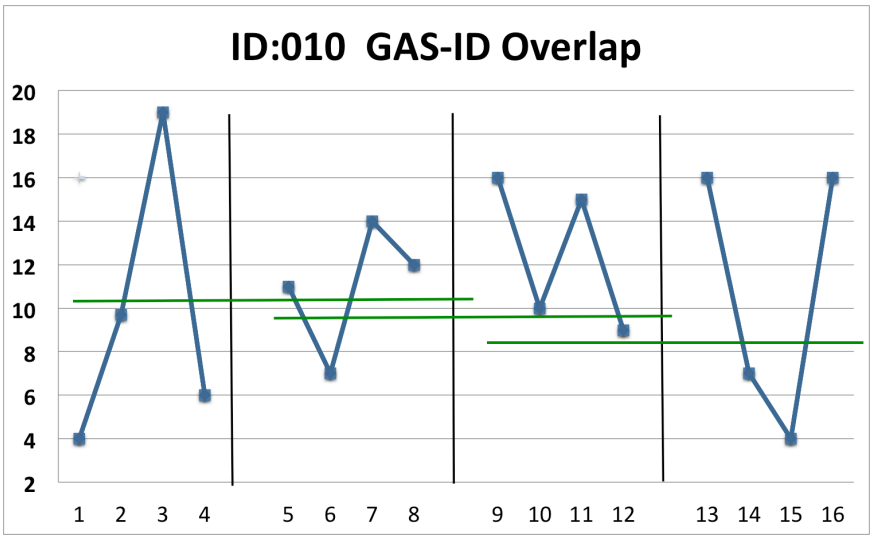
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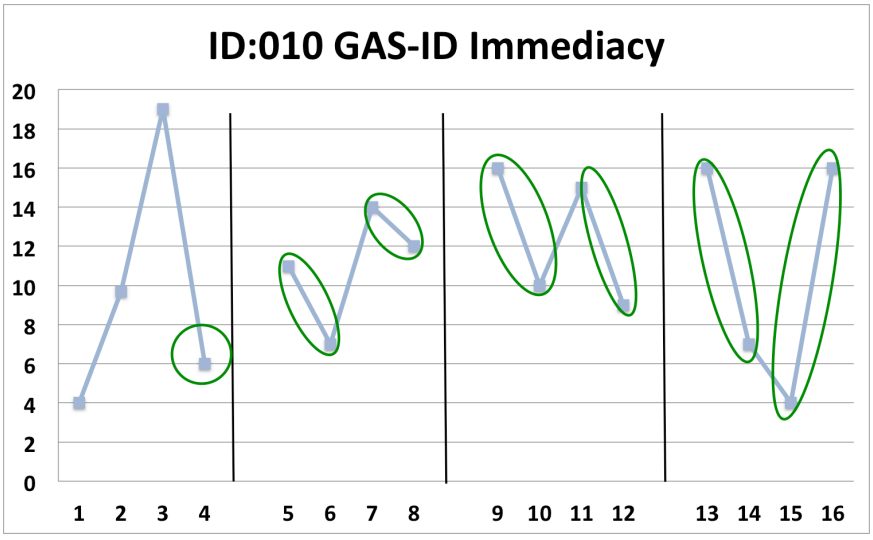
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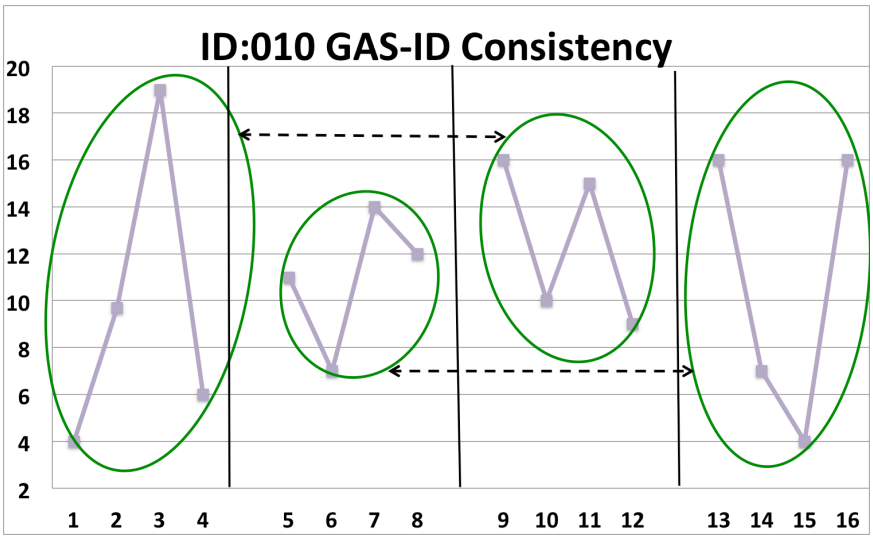
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

week	SAINT	GDS-LD	GAS-ID
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2	0	0	0
3	0	2	0
4	0	0	0
5	0	1	0
6	8	12	9
7	**4**	**6.5**	**4.5**
8	**4**	**6.5**	**4.5**
9	0	5	5
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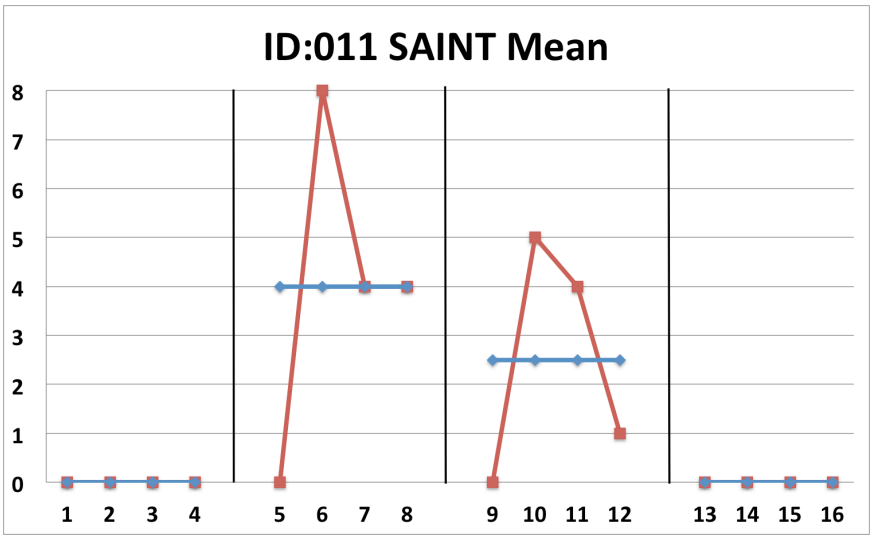
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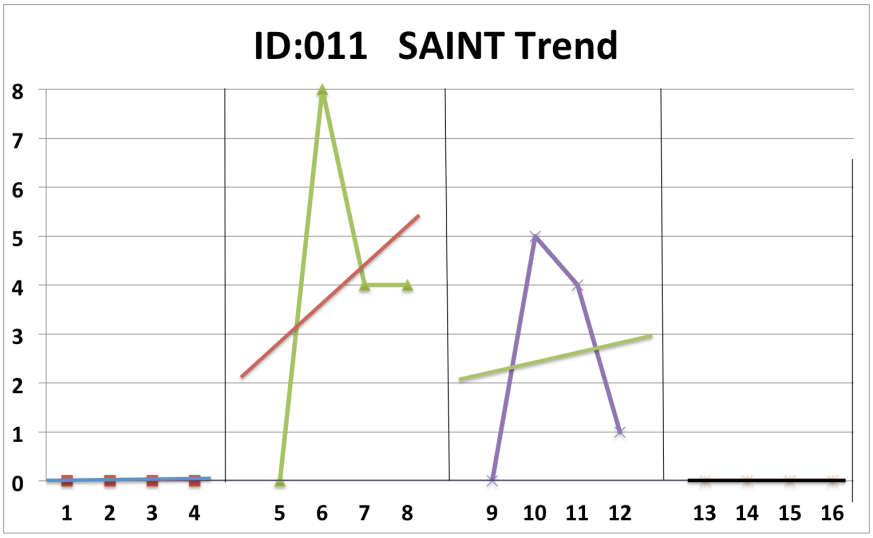
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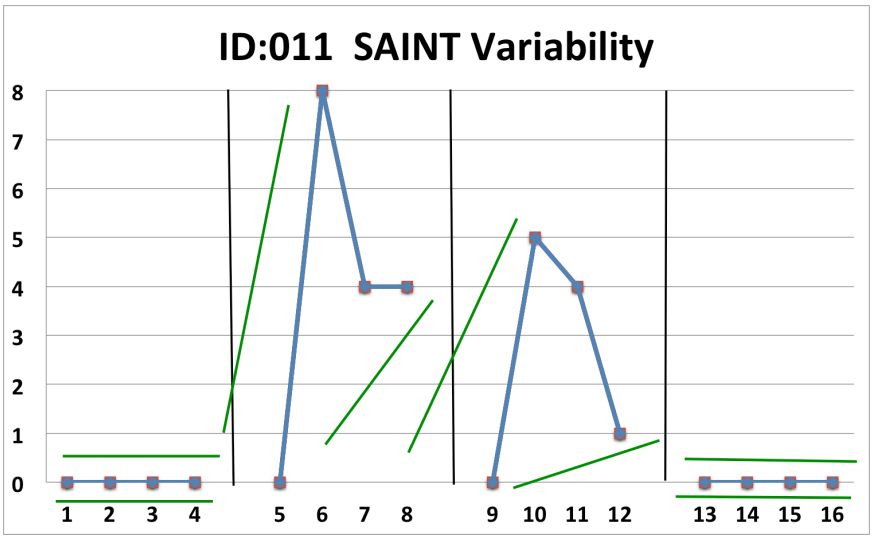
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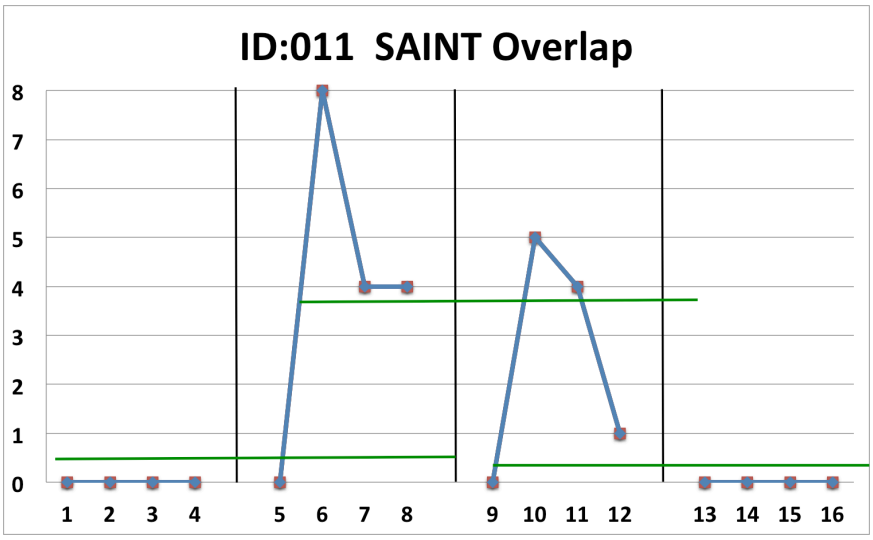
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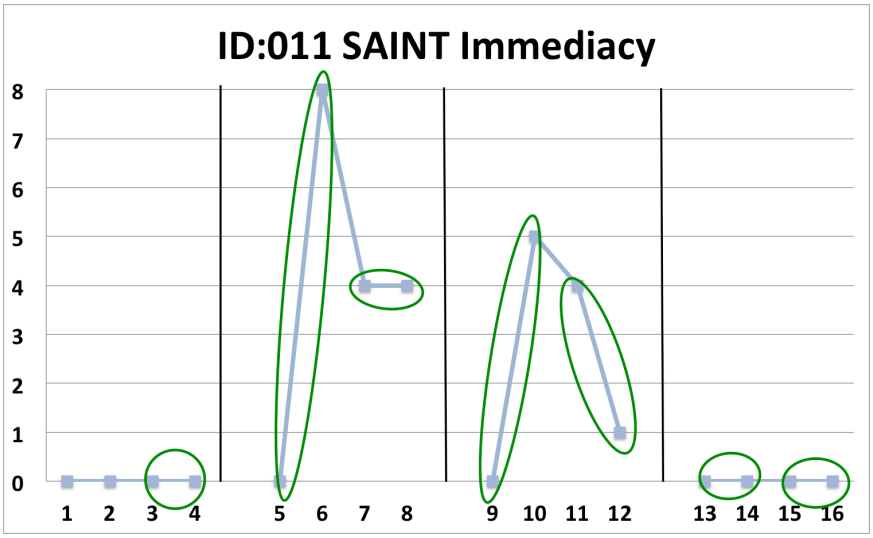
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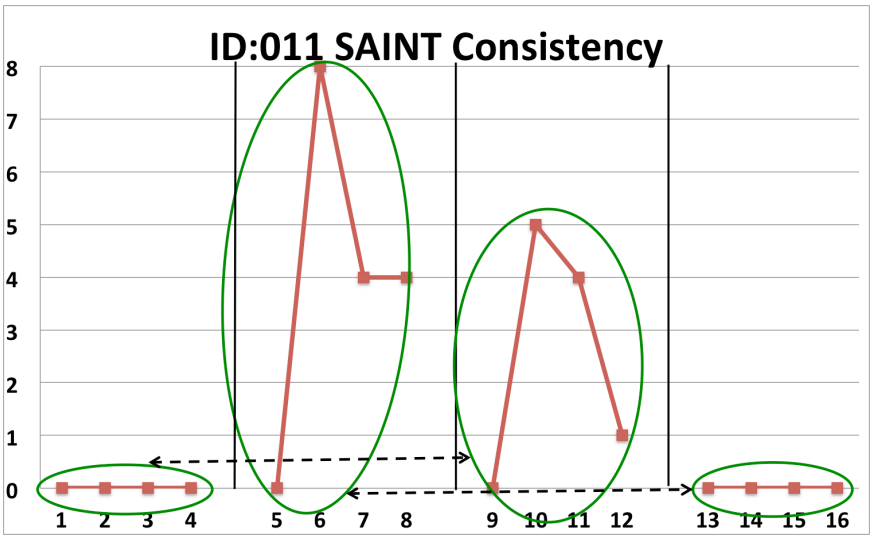
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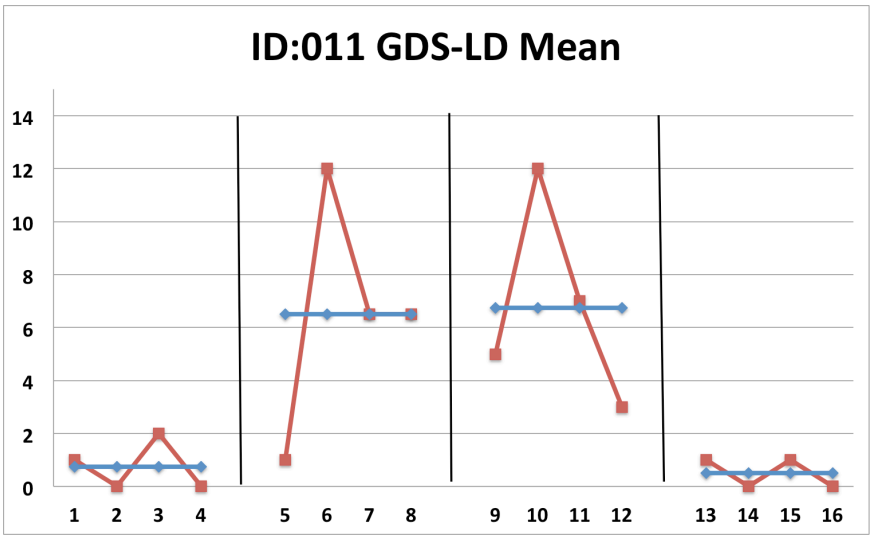
ID:011 GDS-LD Mean
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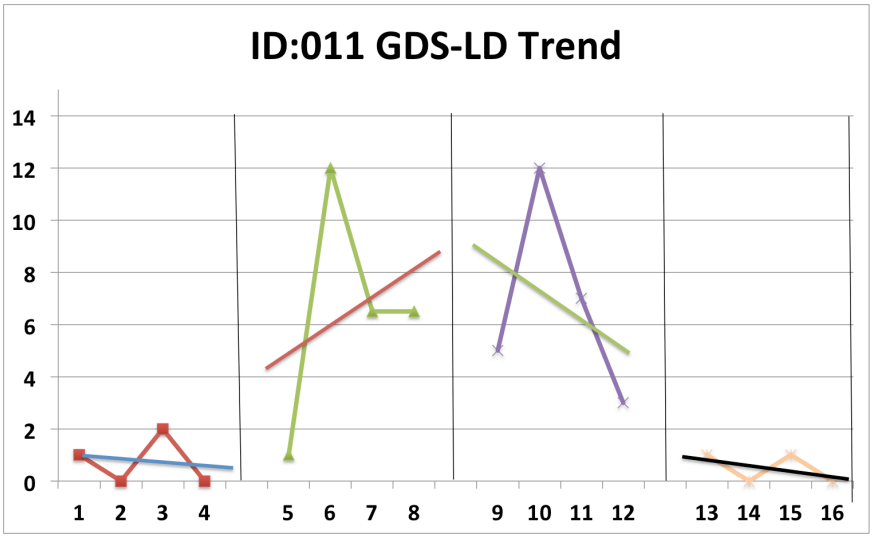
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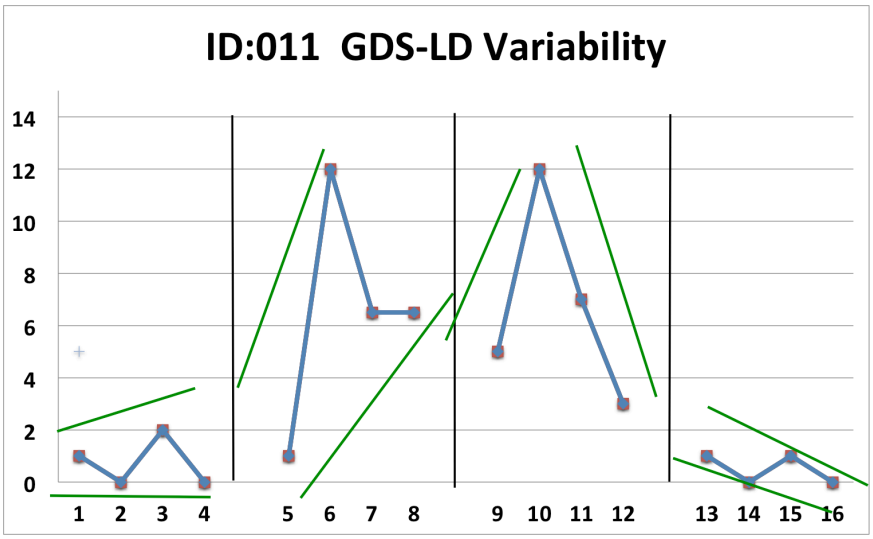
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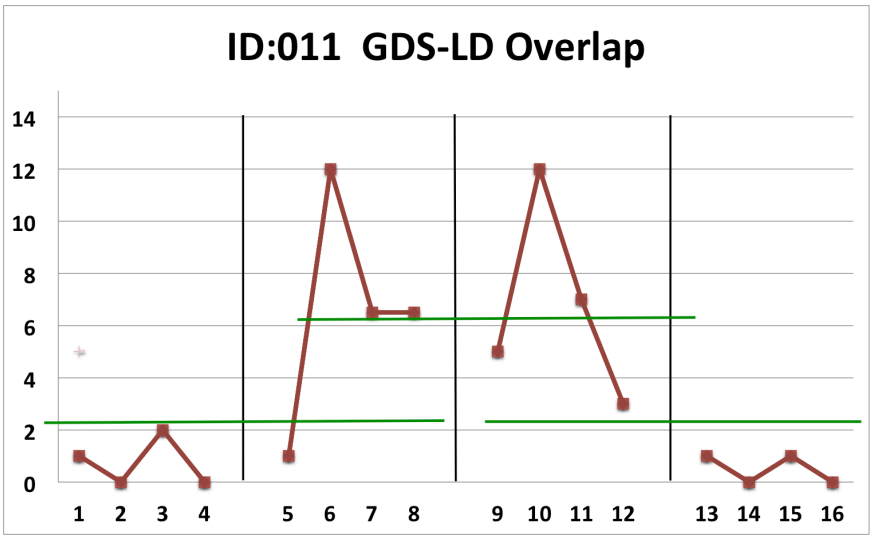
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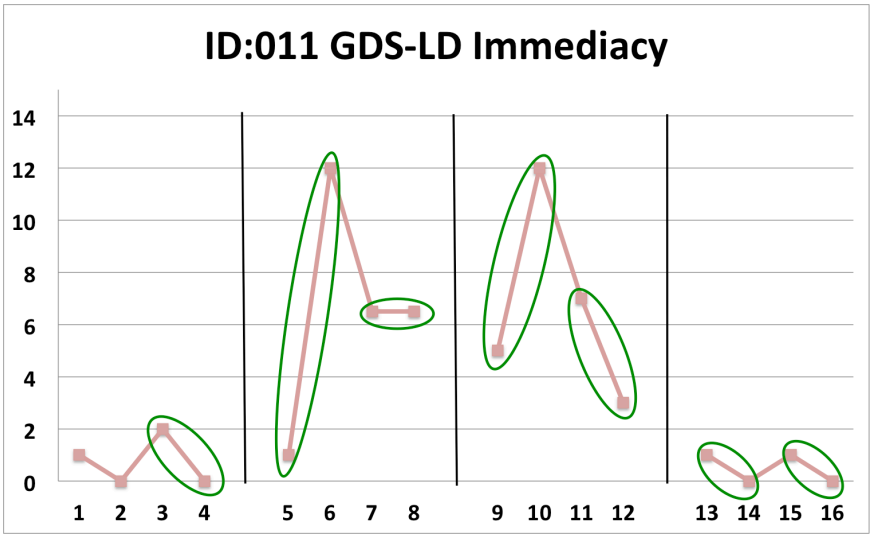
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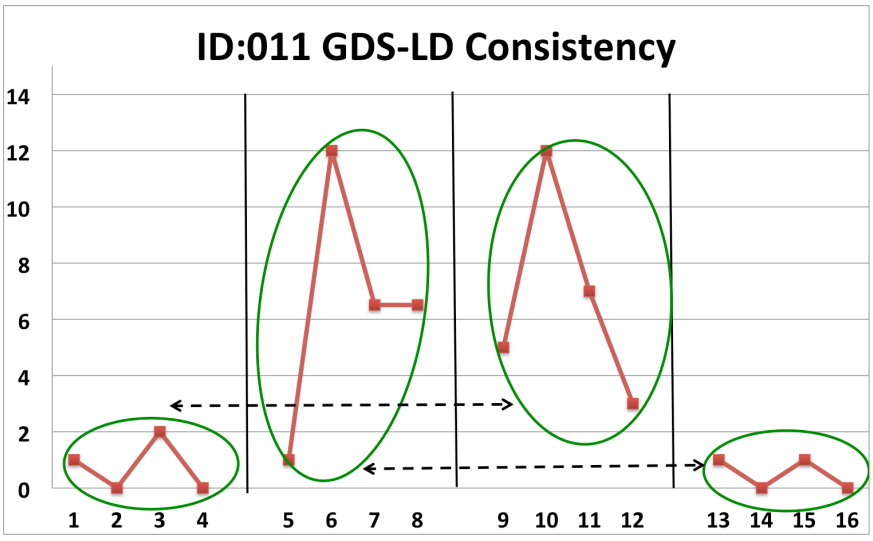
ID:011 GDS-LD Consistency
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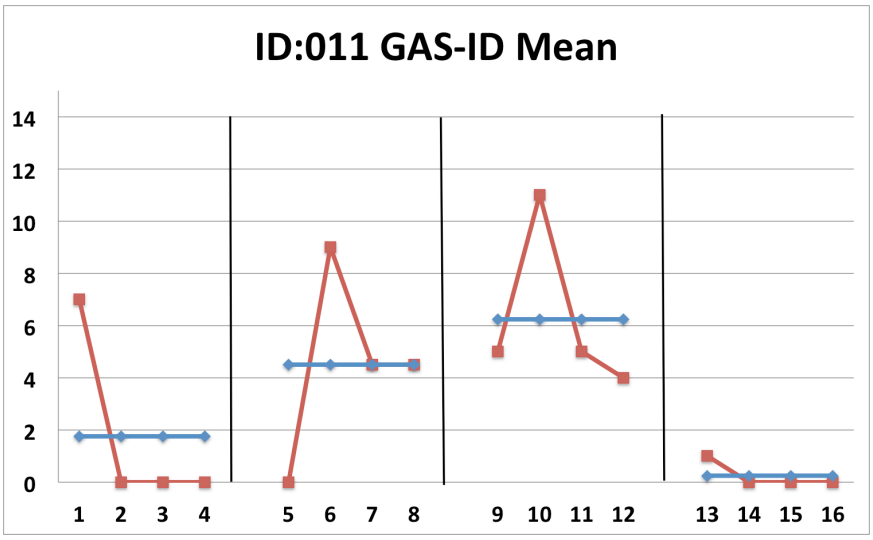
ID:011 GAS-ID Mean
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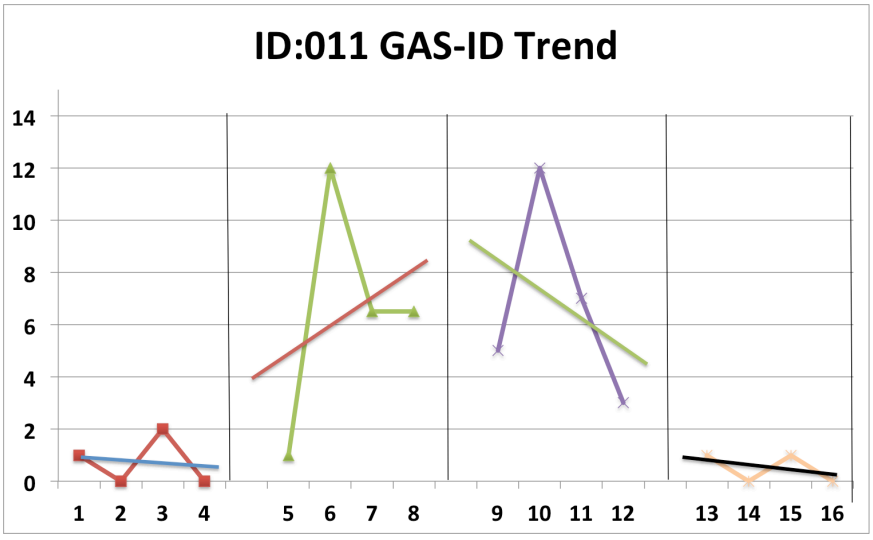
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16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8
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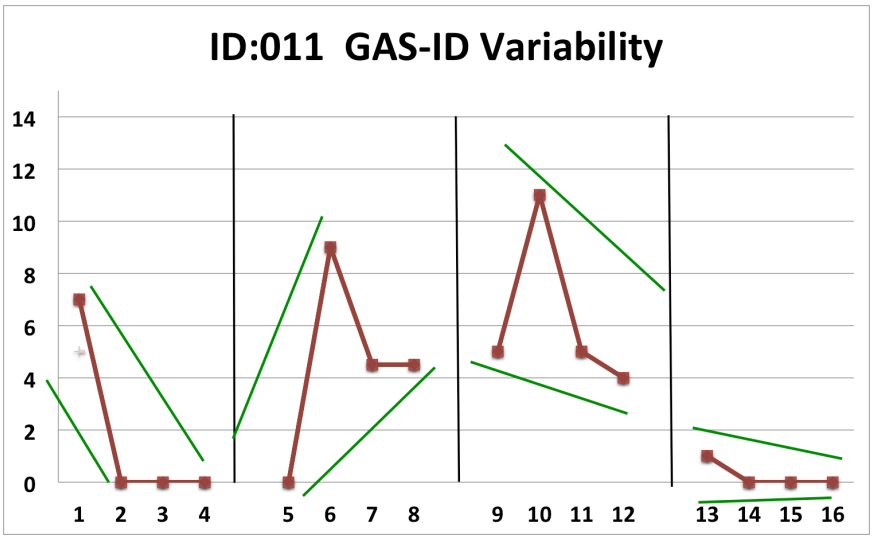
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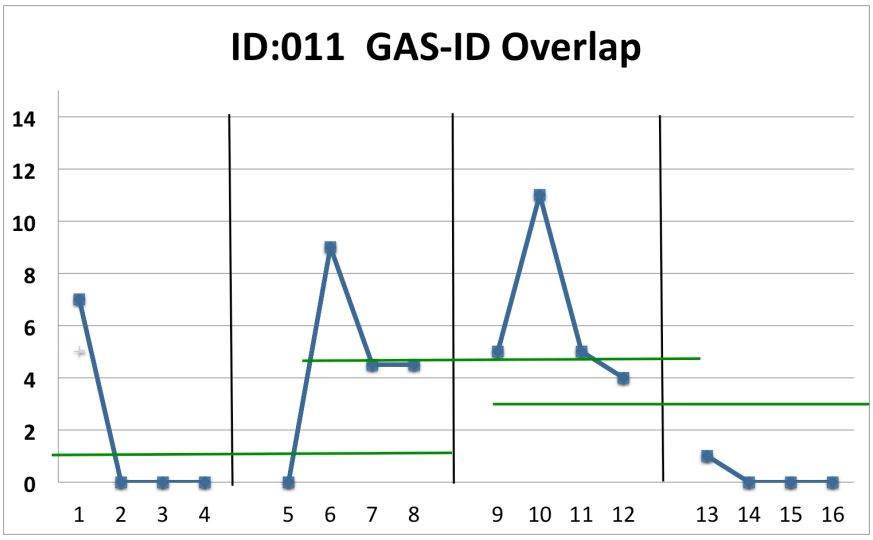
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:011 GAS-ID Overlap
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8
6
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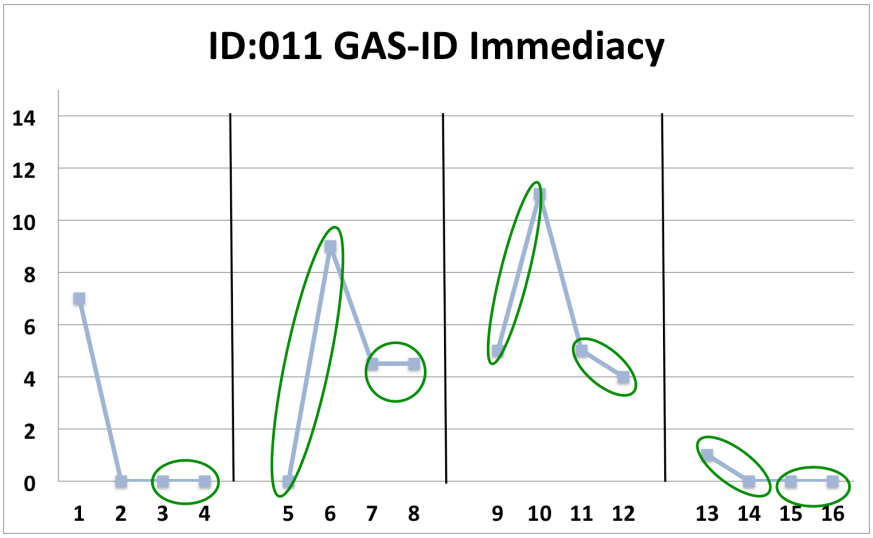
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:011 GAS-ID Immediacy
14
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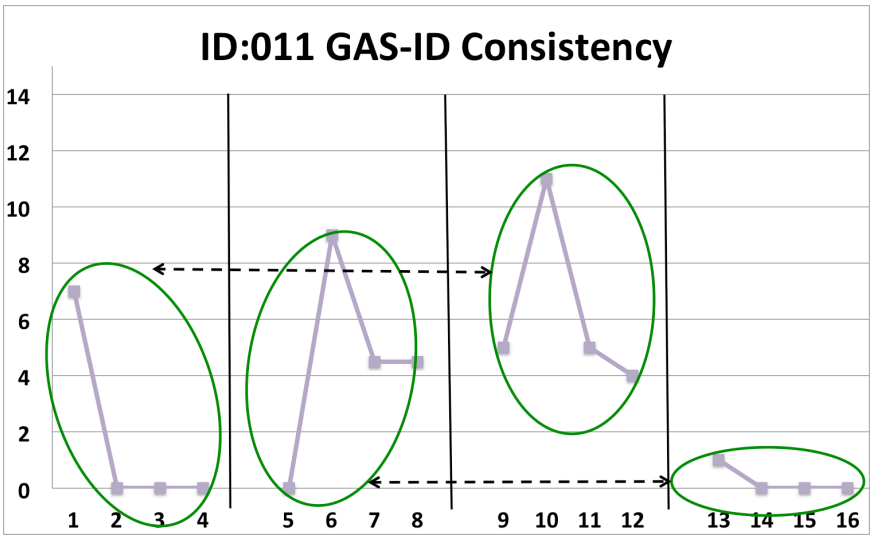
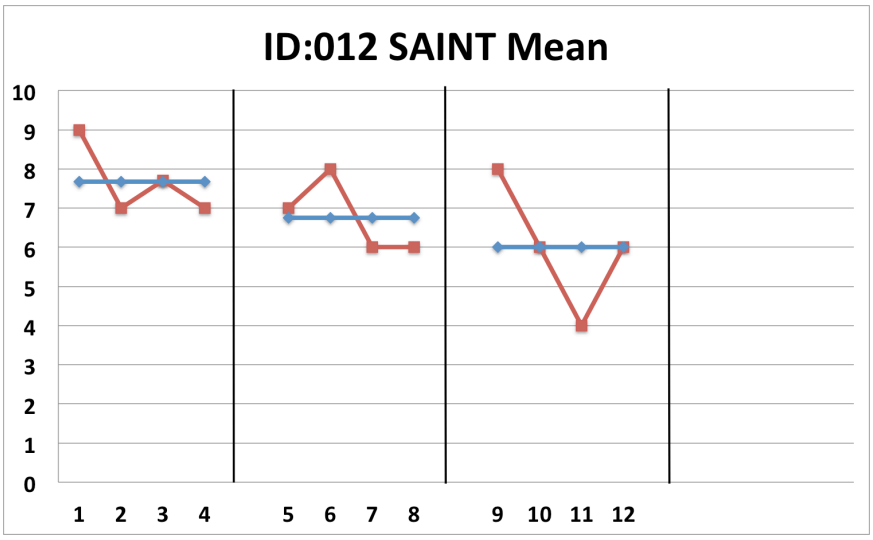
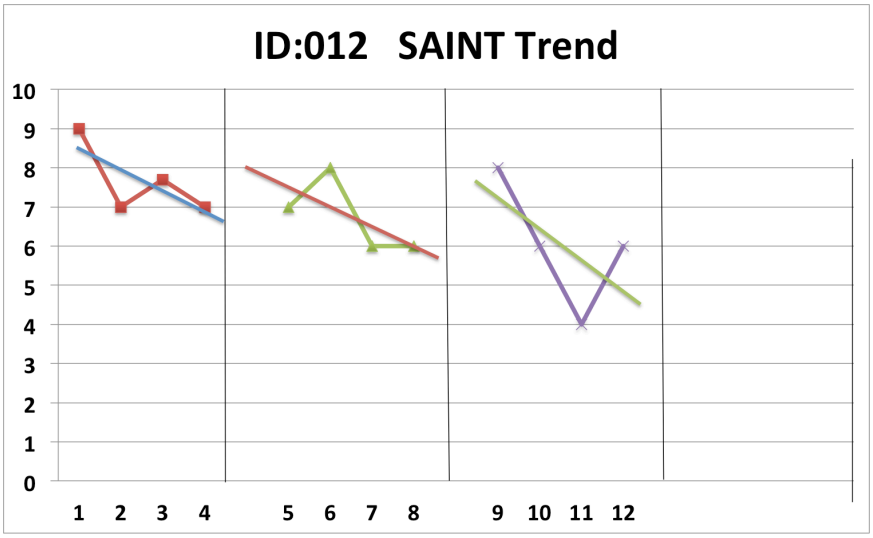
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:011 GAS-ID Consistency
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

ID-12 WEEKLY SCORES AND VISUAL ANALYSIS

	SAINT	GDS-LD	GAS-ID
1	9	13	13
2	7	13	9
3	**7.7**	**12.7**	**9.7**
4	7	12	7
5	7	17	9
6	8	15	12
7	6	12	9
8	6	11	8
9	8	16	9
10	**6**	**11.5**	**8.5**
11	4	7	8
12	**6**	**11.5**	**8.5**
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**


ID:012 SAINT Mean
10
9
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12


ID:012 SAINT Trend
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9
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6
5
4
3
2
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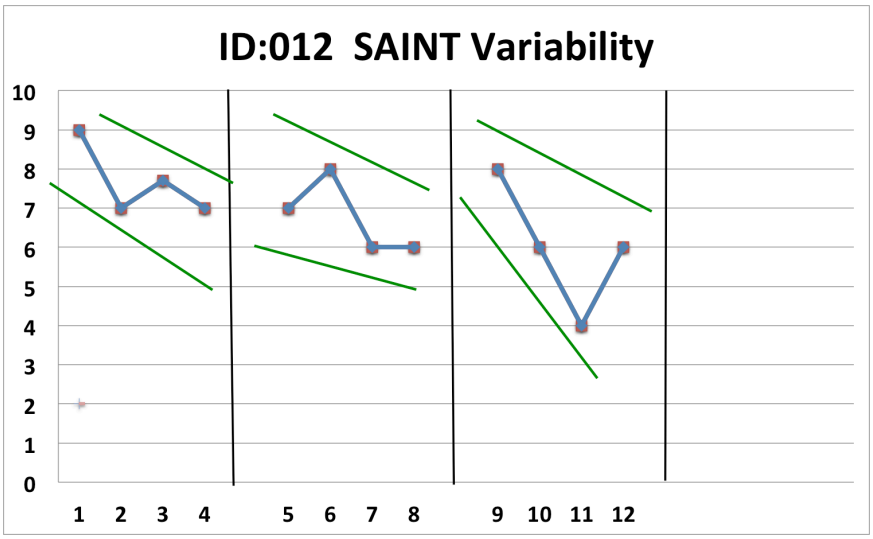
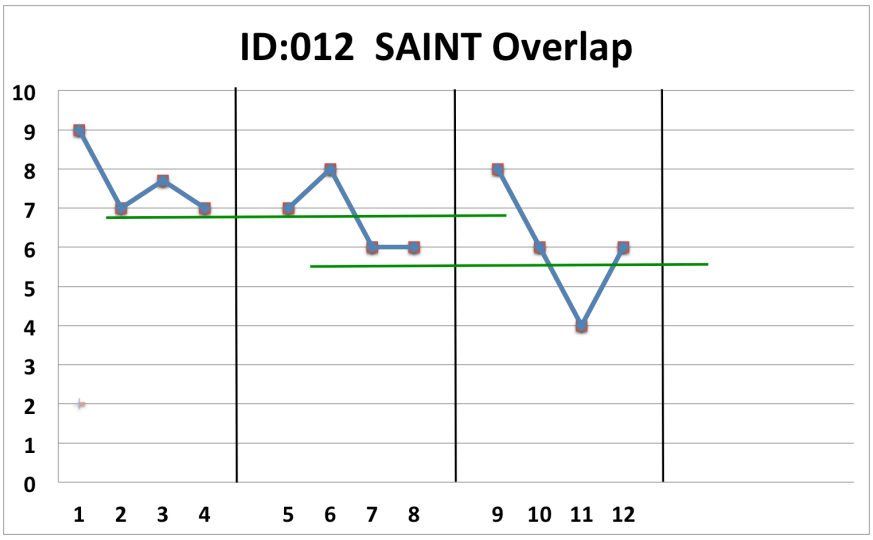
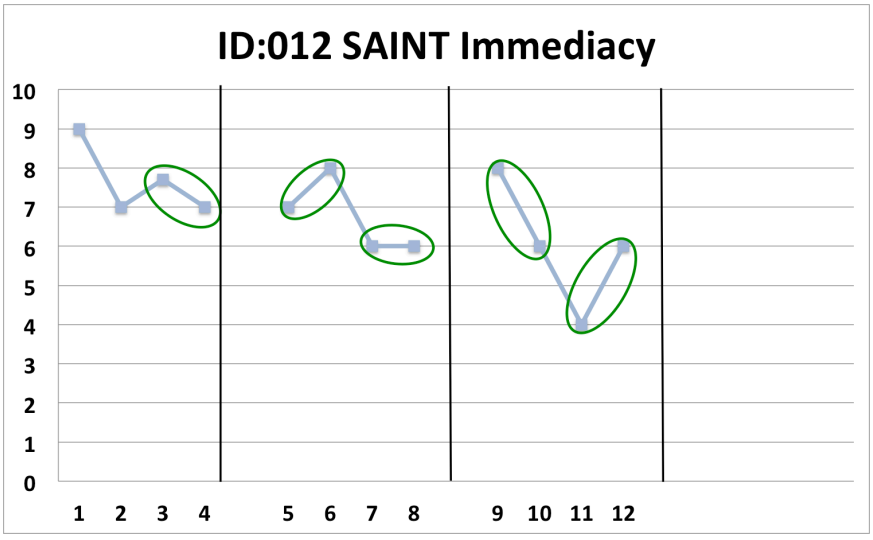
0
1 2 3 4 5 6 7 8 9 10 11 12


ID:012 SAINT Variability
10
9
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12


ID:012 SAINT Overlap
10
9
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12


ID:012 SAINT Immediacy
10
9
8
7
6
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4
3
2
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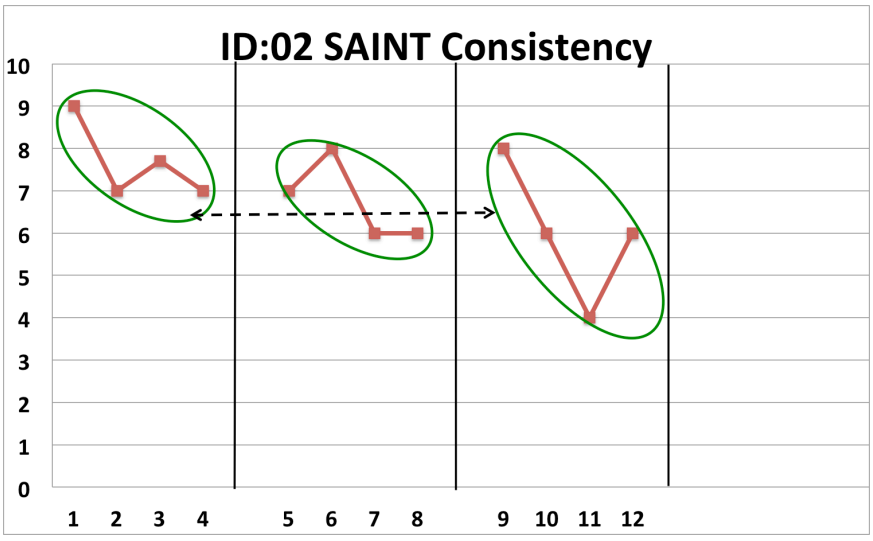
0
1 2 3 4 5 6 7 8 9 10 11 12


ID:02 SAINT Consistency
10
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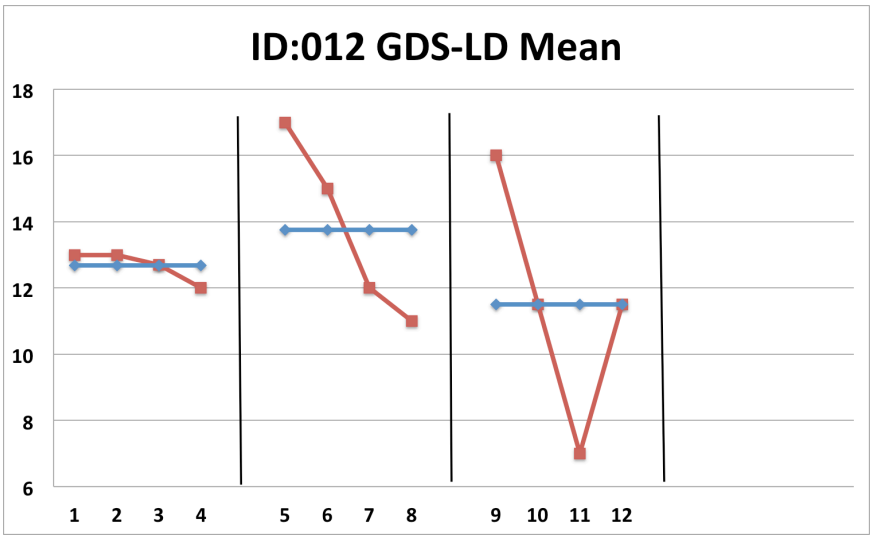
ID:012 GDS-LD Mean
18
16
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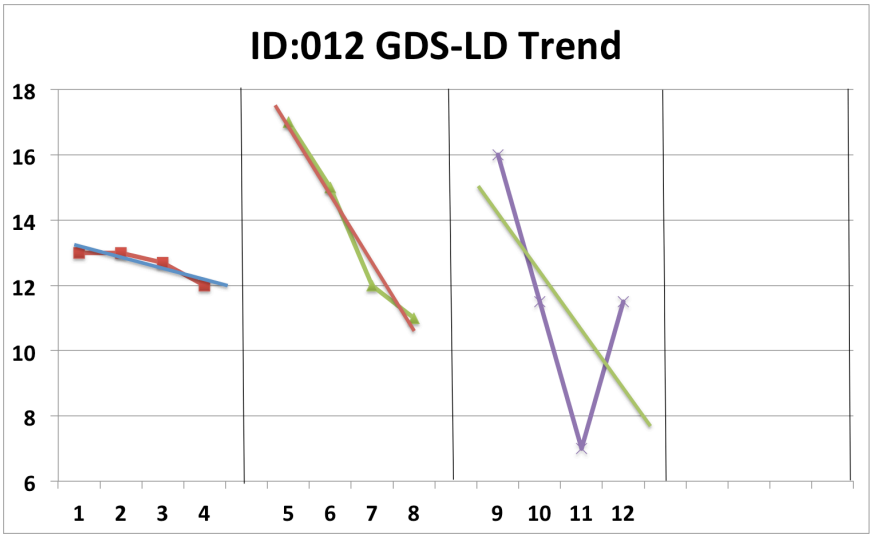
12
10
8
6
1 2 3 4 5 6 7 8 9 10 11 12


ID:012 GDS-LD Trend
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8
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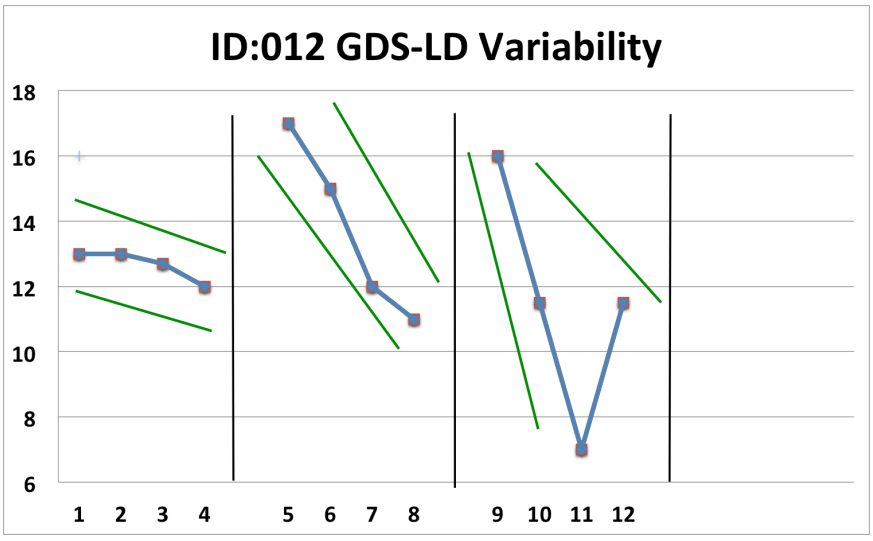
1 2 3 4 5 6 7 8 9 10 11 12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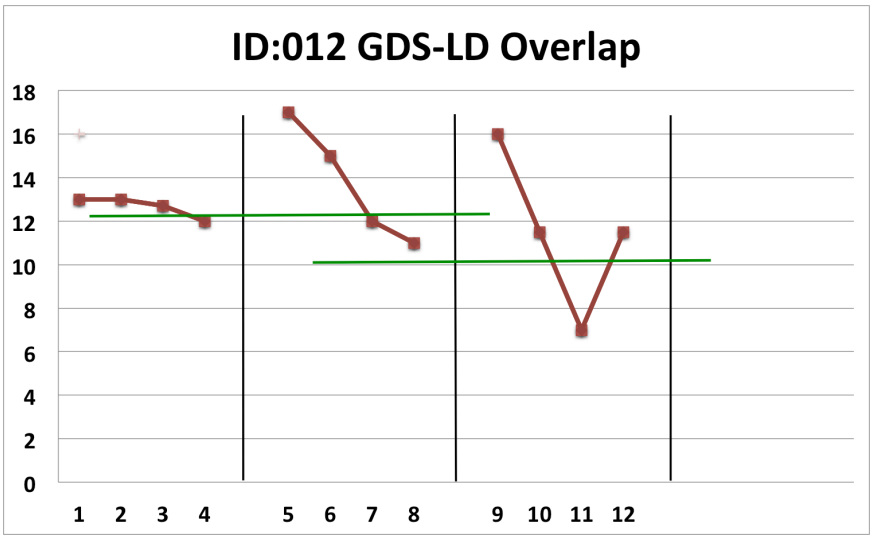
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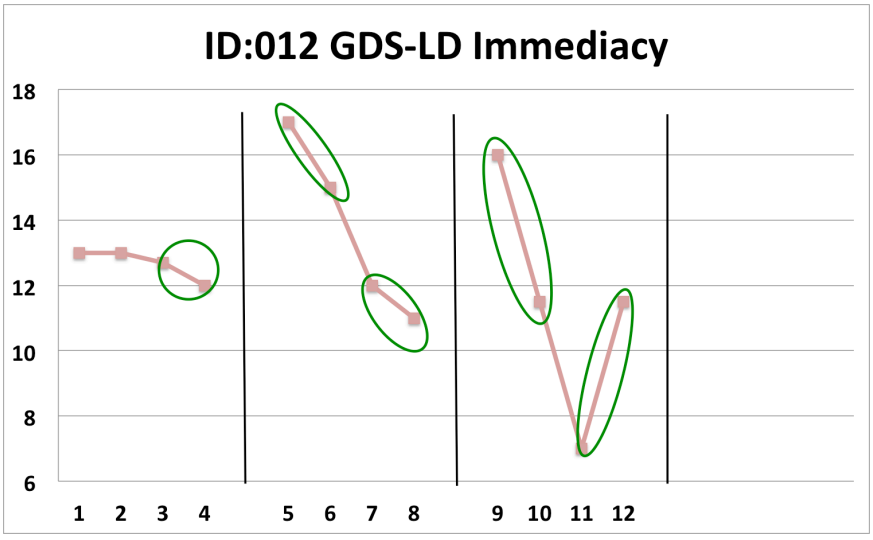
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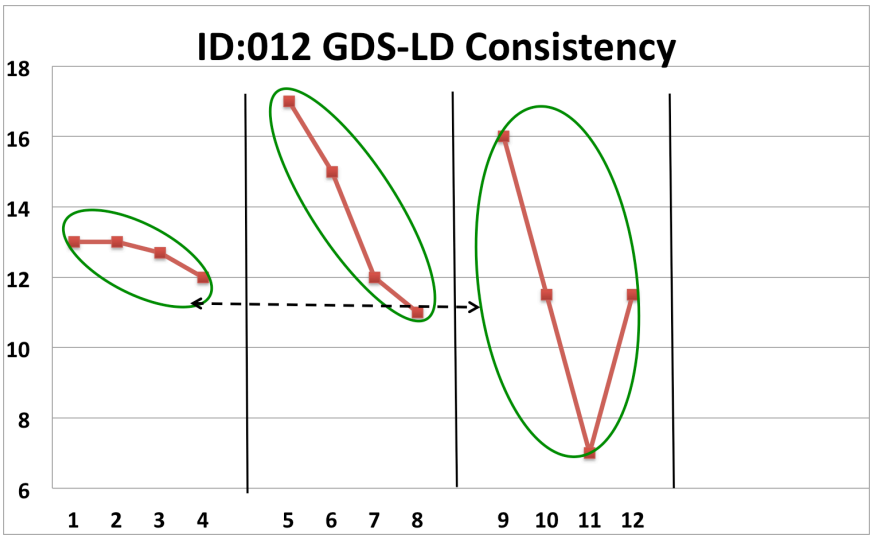
ID:012 GDS-LD Consistency
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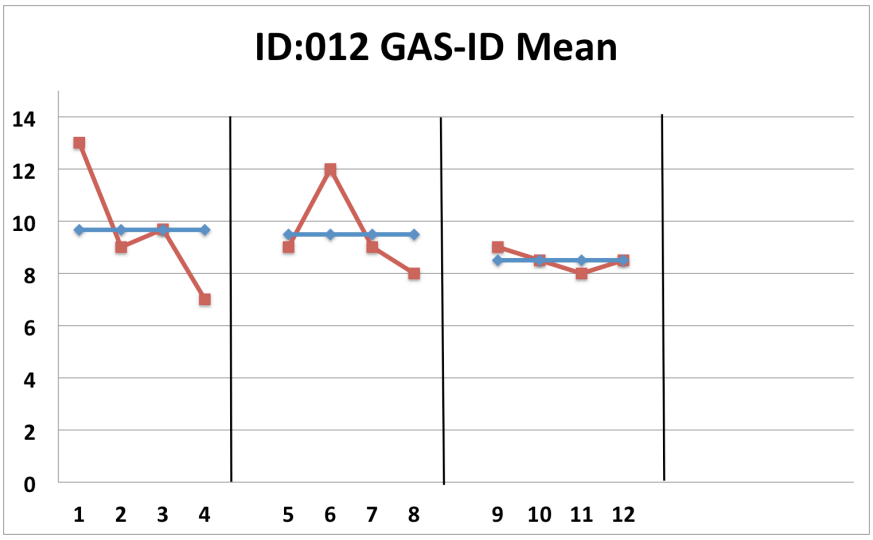
1 2 3 4 5 6 7 8 9 10 11 12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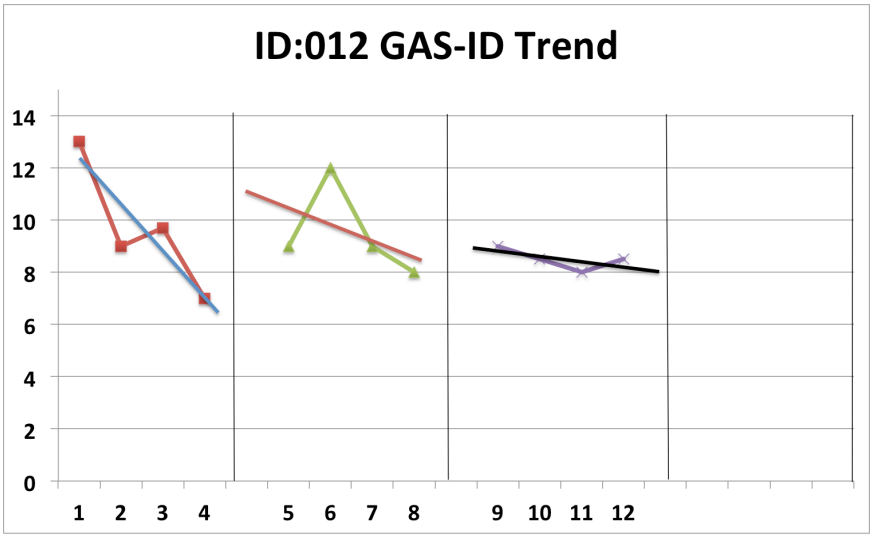
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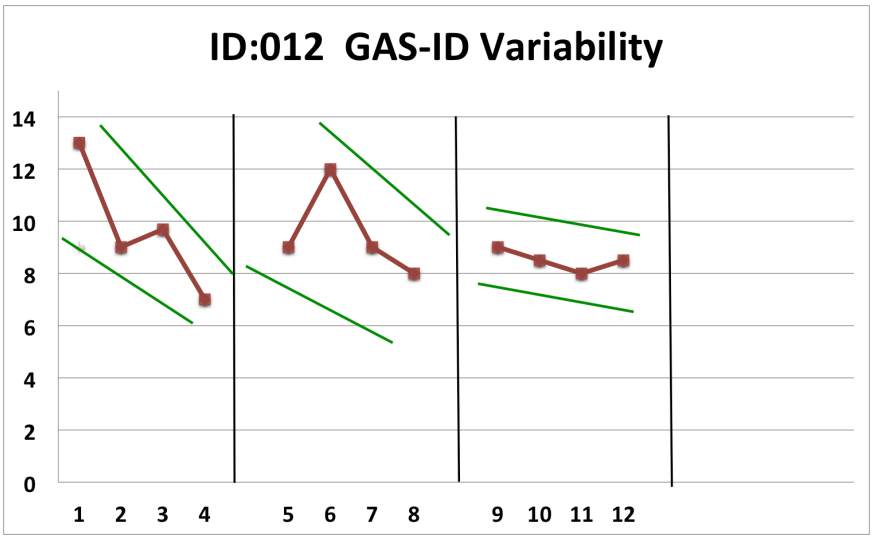
ID:012 GAS-ID Variability
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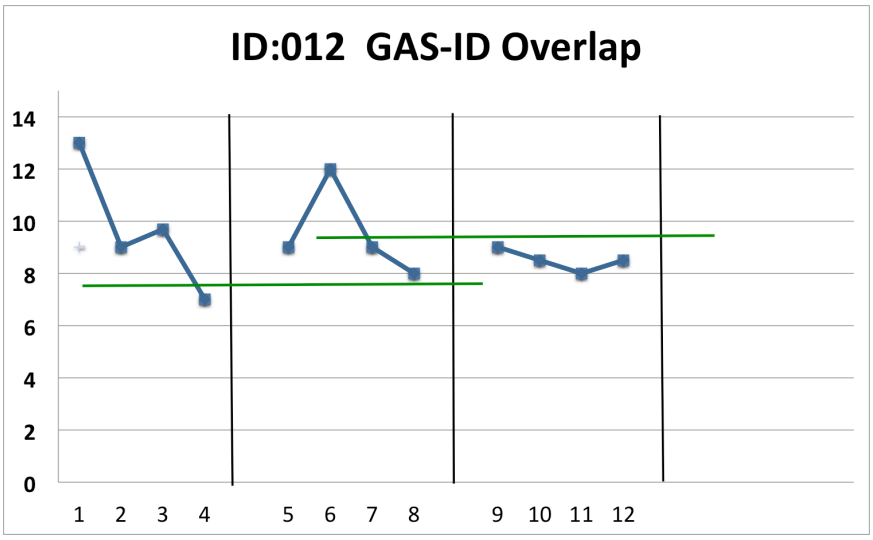
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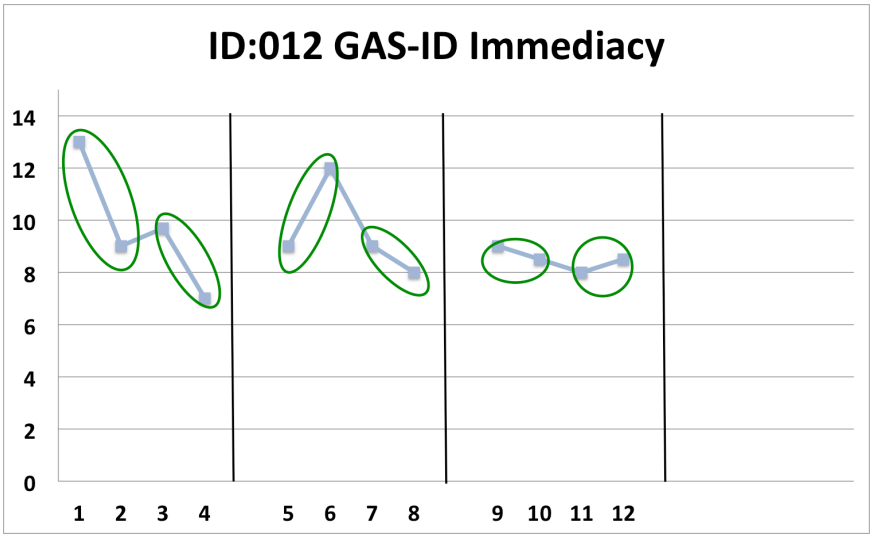
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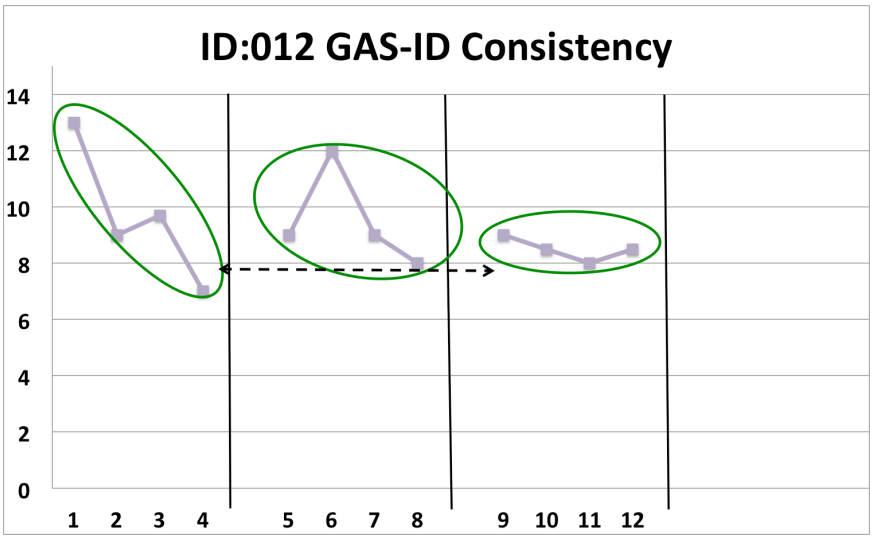
ID:012 GAS-ID Consistency
14
12
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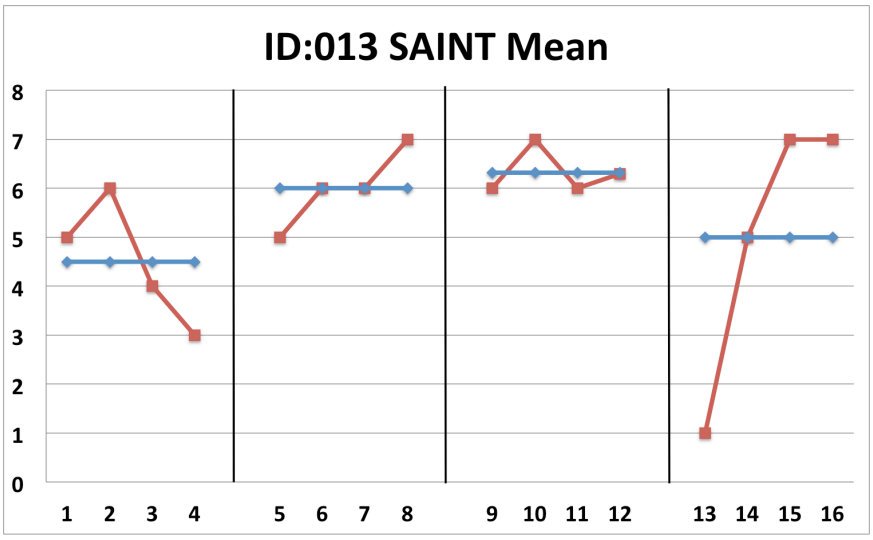
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12

ID-13 WEEKLY SCORES AND VISUAL ANALYSIS

	SAINT	GDS-LD	GAS-ID
1	5	19	11
2	6	20	8
3	4	17	9
4	3	15	10
5	5	19	10
6	6	16	11
7	**6**	**17.3**	**11.3**
8	7	17	13
9	6	17	11
10	7	20	10
11	6	17	9
12	**6.3**	**18**	**10**
13	1	4	2
14	**5**	**16**	**9.3**
15	7	19	13
16	7	25	13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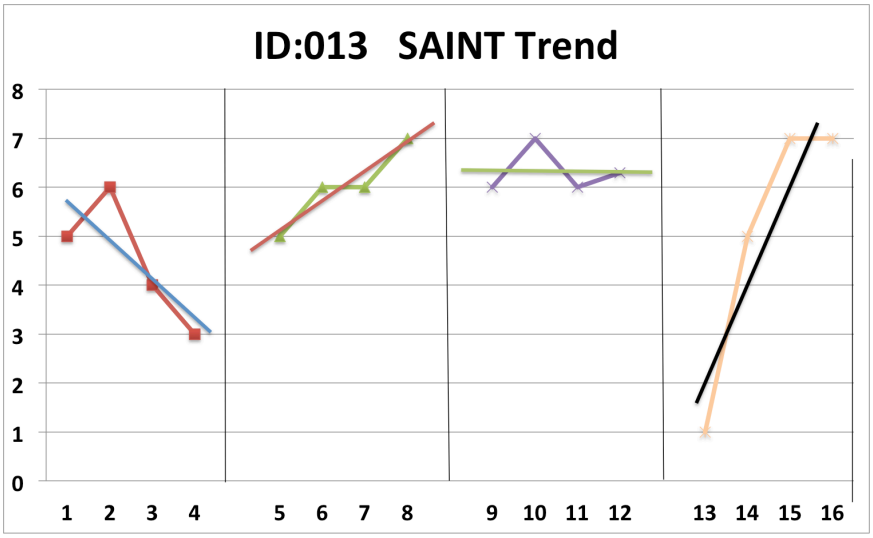
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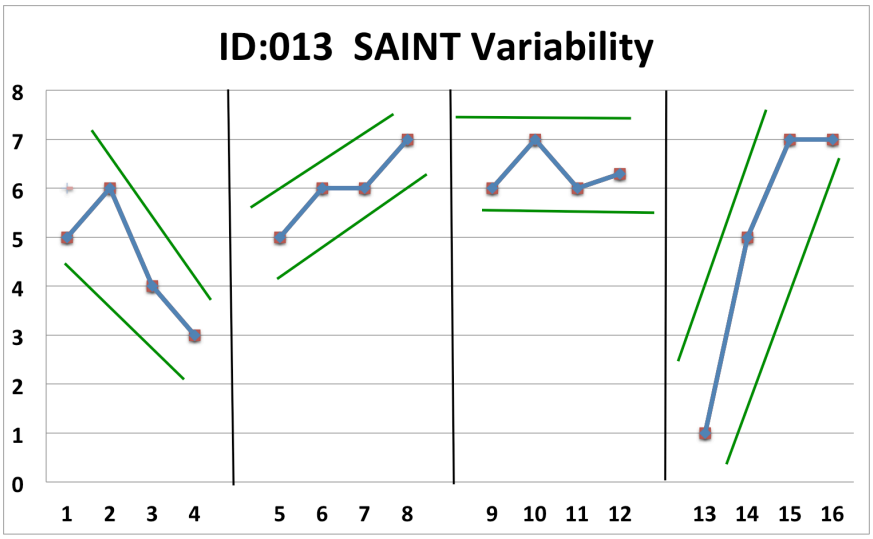
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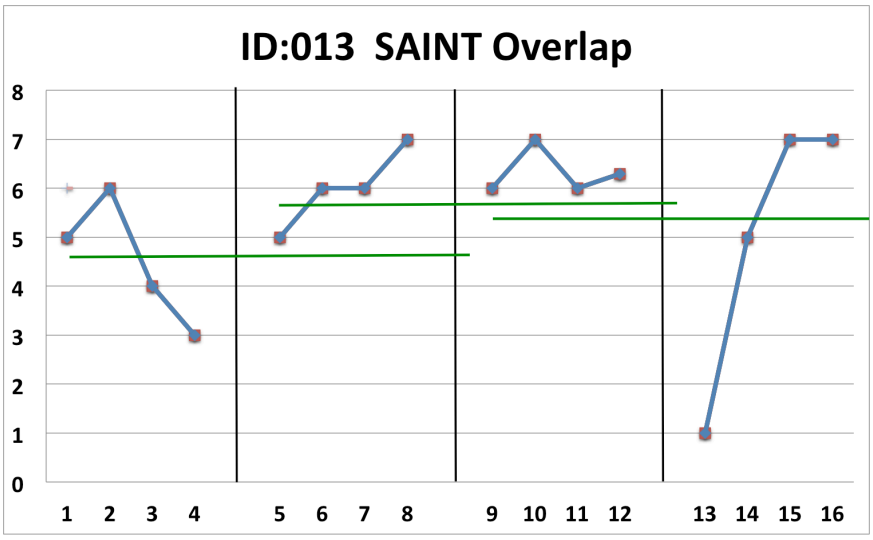
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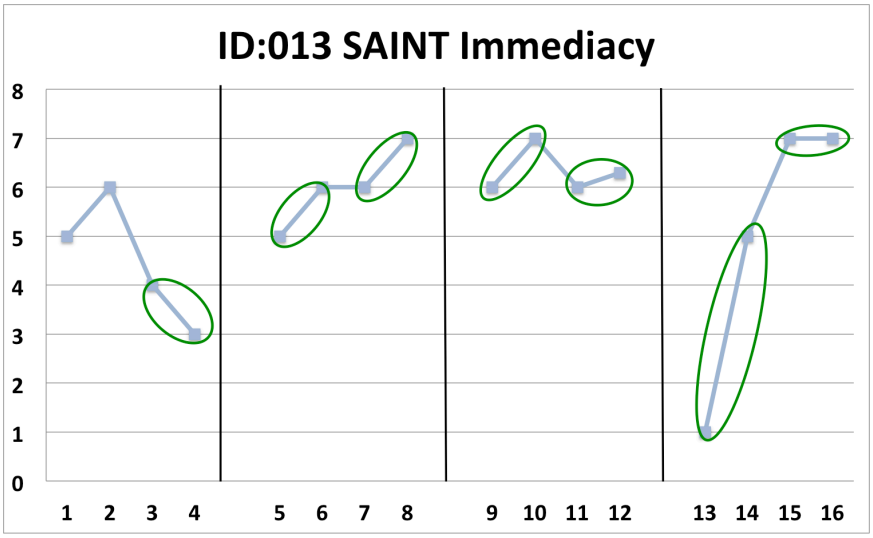
ID:013 SAINT Immediacy
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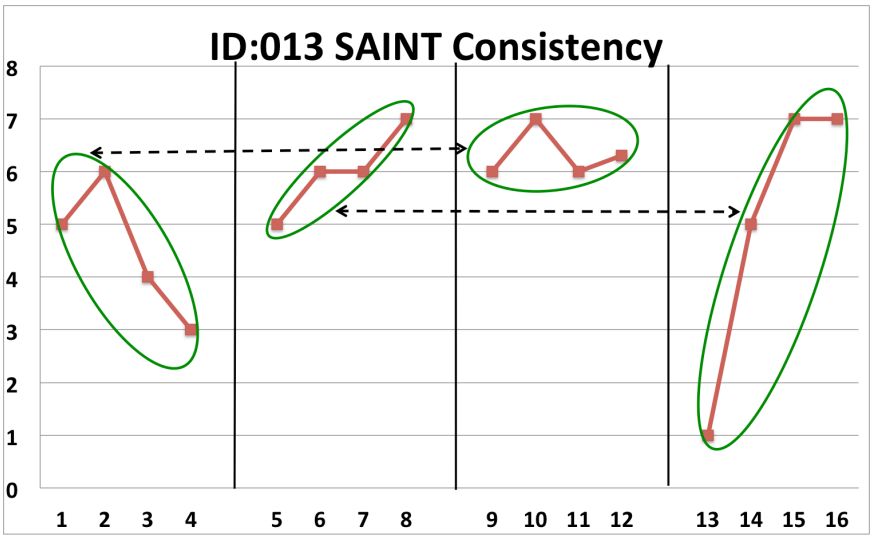
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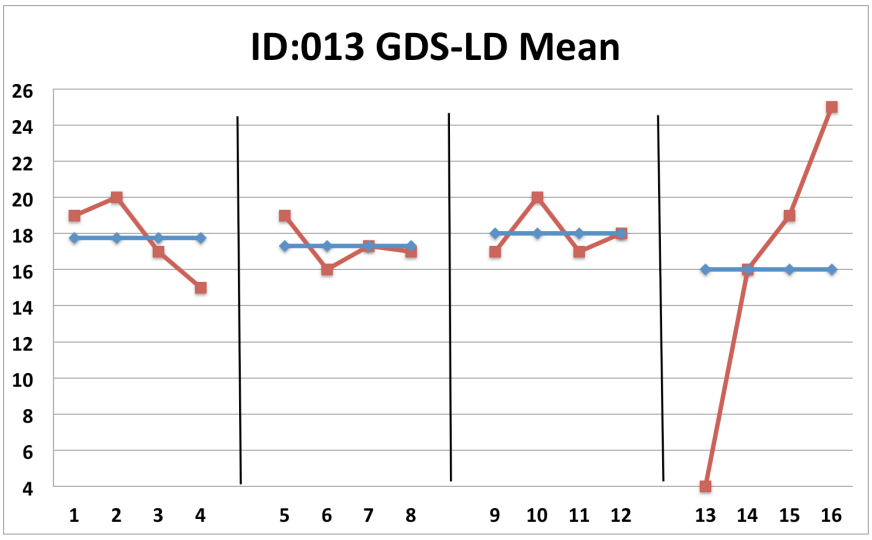
ID:013 GDS-LD Mean
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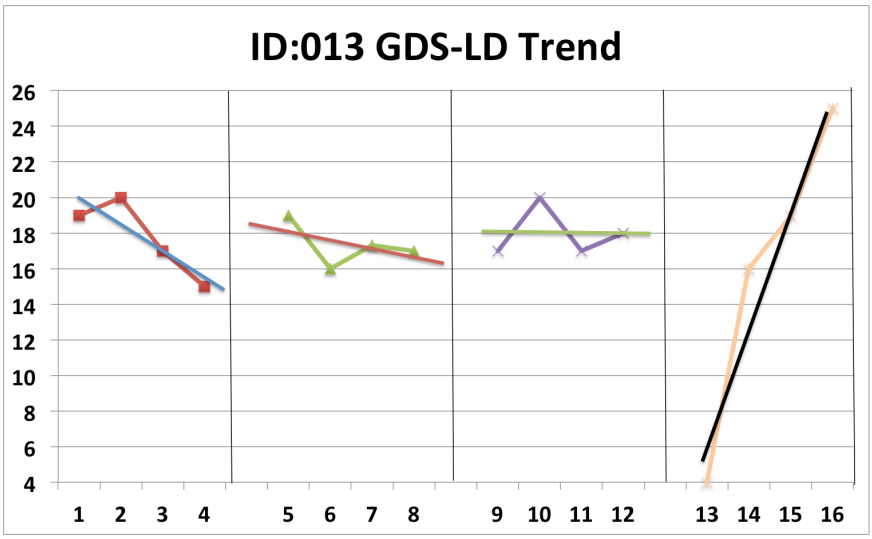
8
6
4
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:013 GDS-LD Trend
26
24
22
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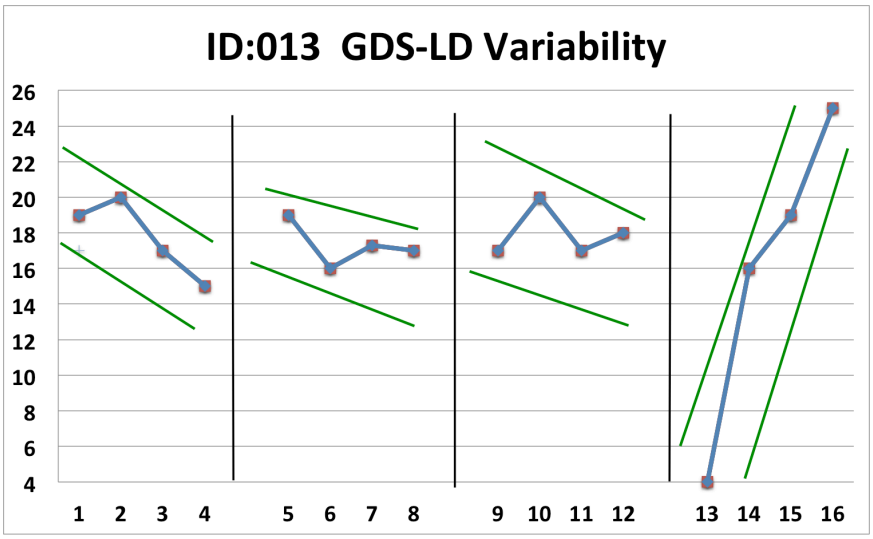
18
16
14
12
10
8
6
4
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:013 GDS-LD Variability
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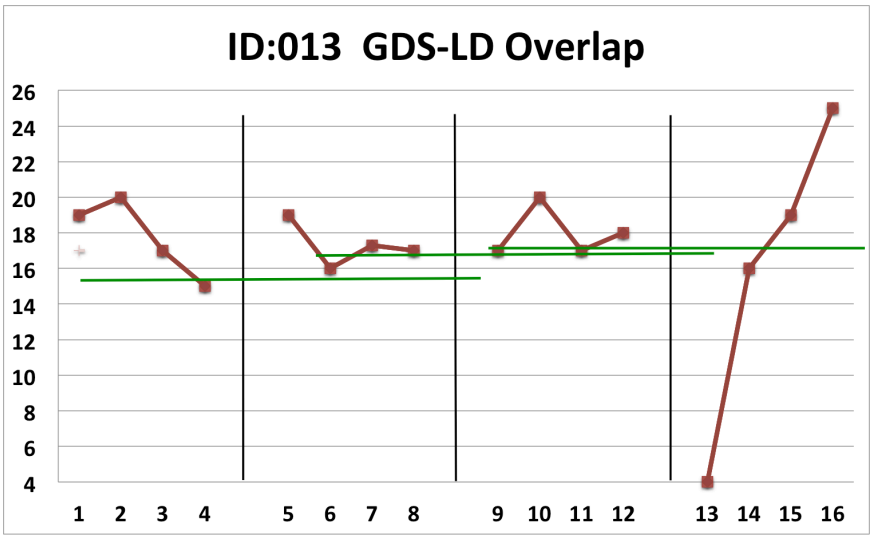
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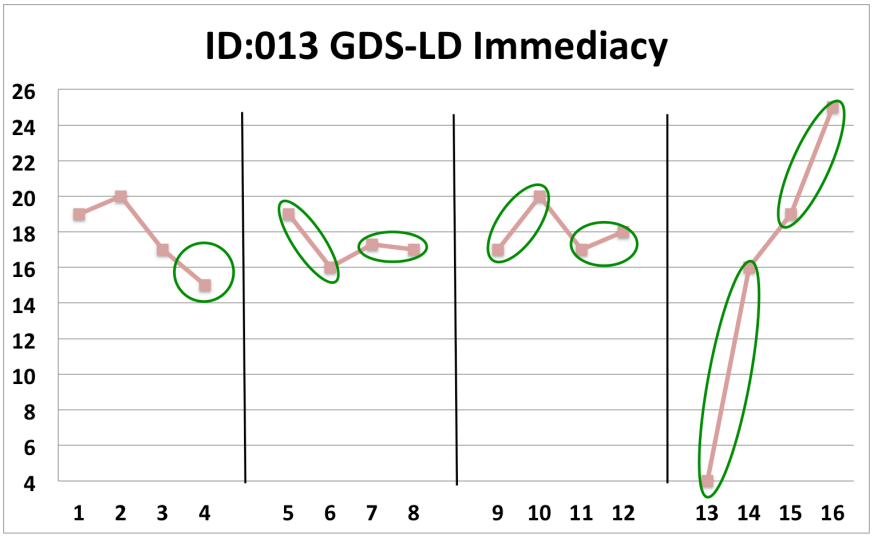
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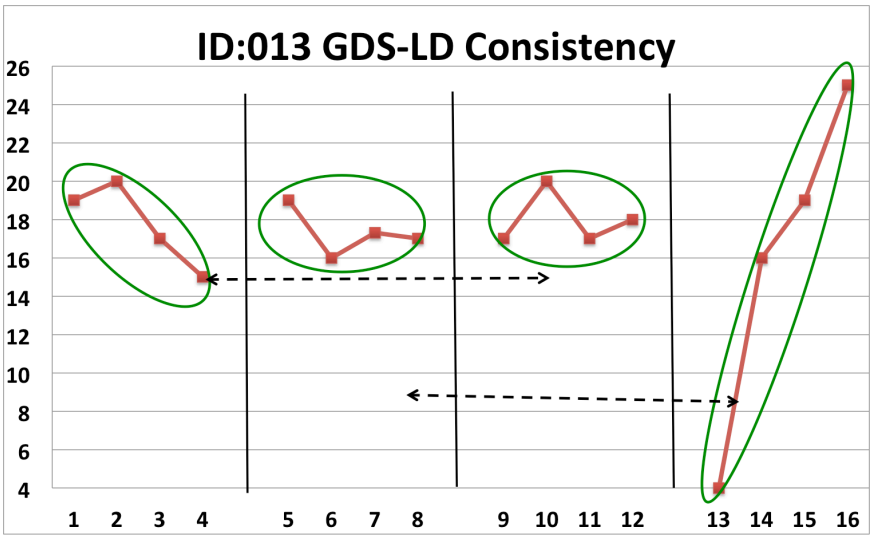
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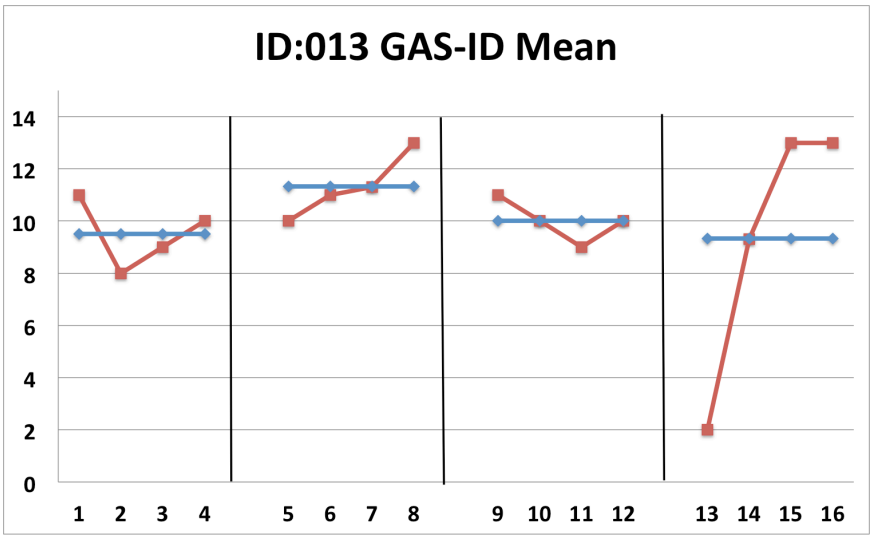
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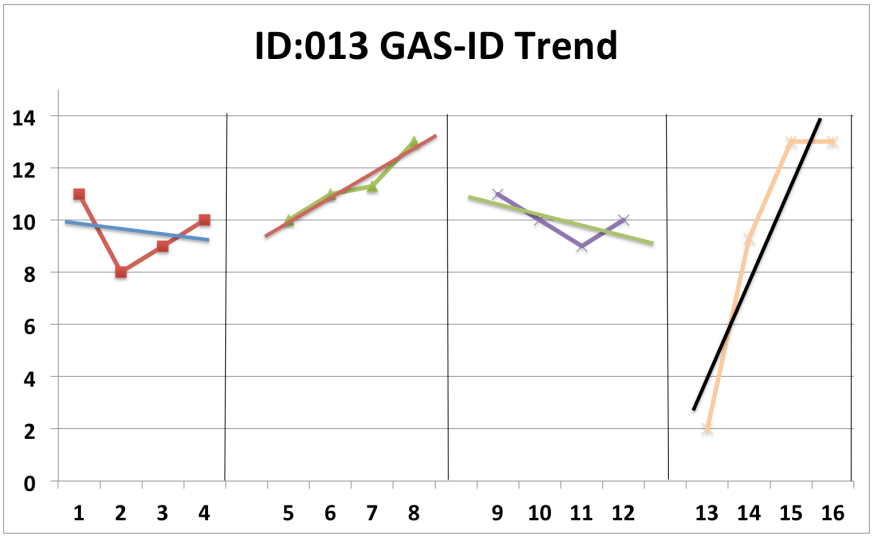
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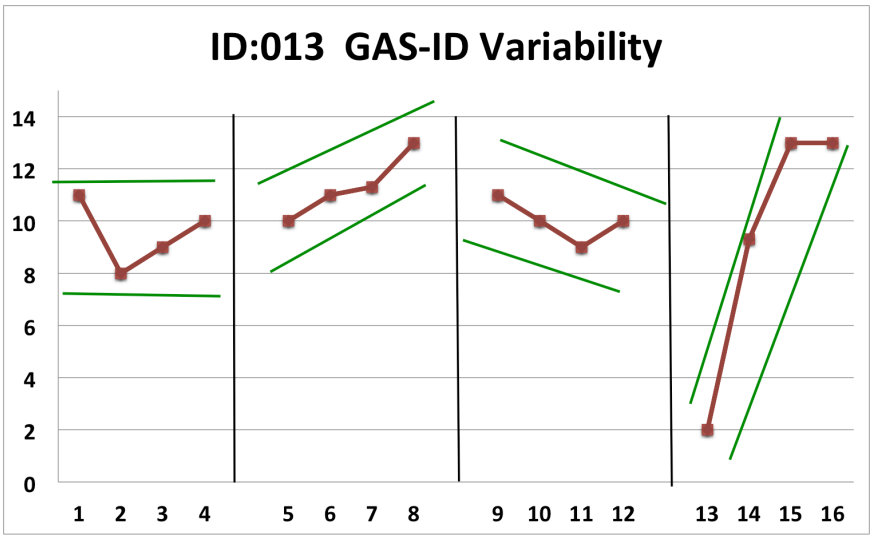
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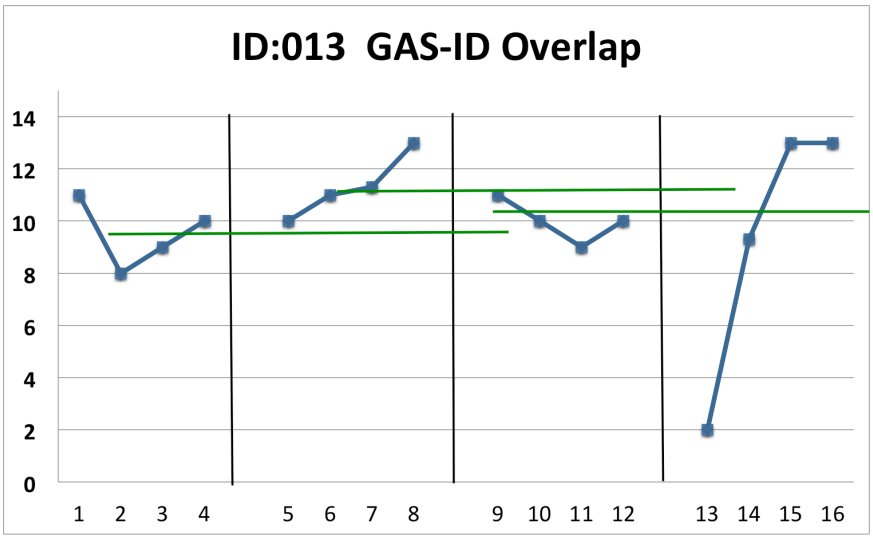
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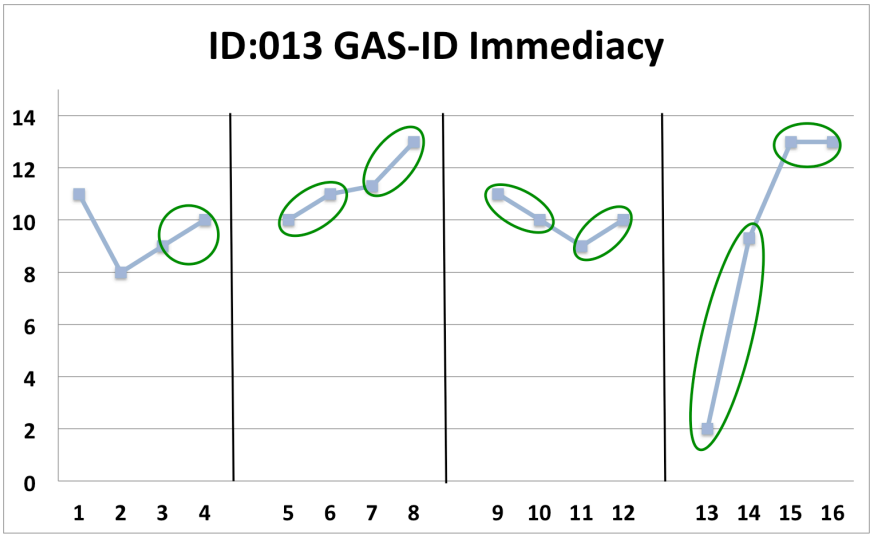
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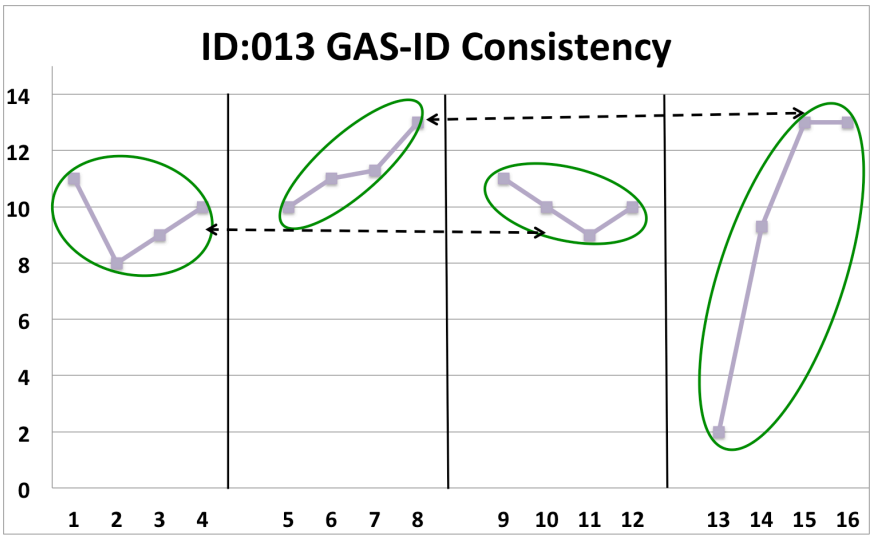
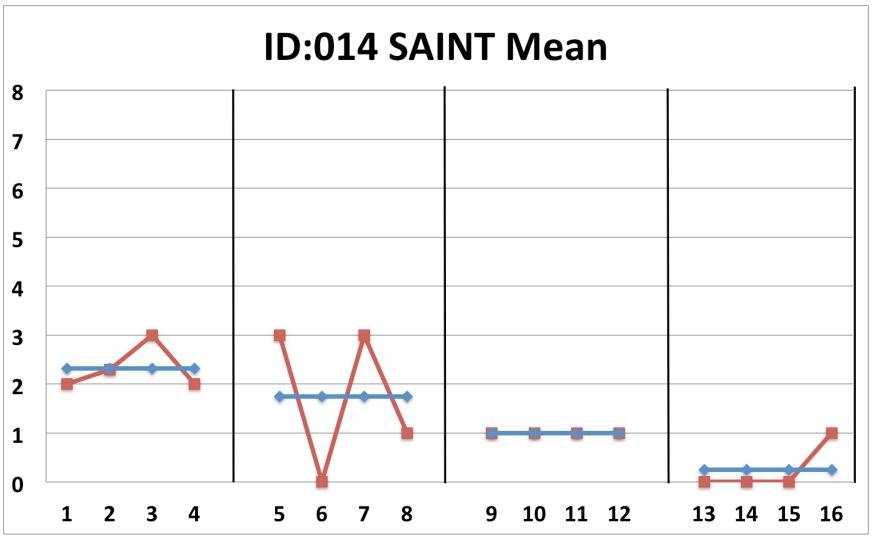
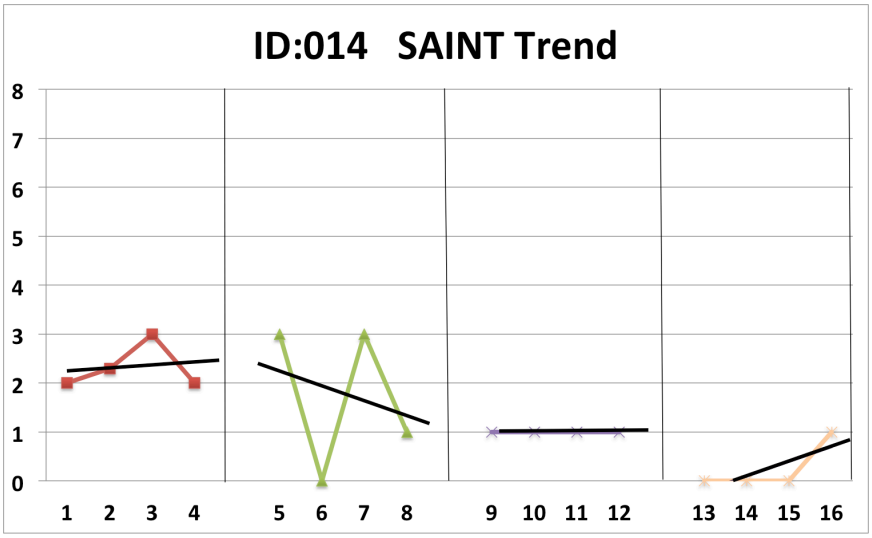

ID:013 GAS-ID Consistency
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

ID-14 WEEKLY SCORES AND VISUAL ANALYSIS

	SAINT	GDS-LD	GAS-ID
1	5	19	11
2	6	20	8
3	4	17	9
4	3	15	10
5	5	19	10
6	6	16	11
7	**6**	**17.3**	**11.3**
8	7	17	13
9	6	17	11
10	7	20	10
11	6	17	9
12	**6.3**	**18**	**10**
13	1	4	2
14	**5**	**16**	**9.3**
15	7	19	13
16	7	25	13


ID:014 SAINT Mean
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16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7
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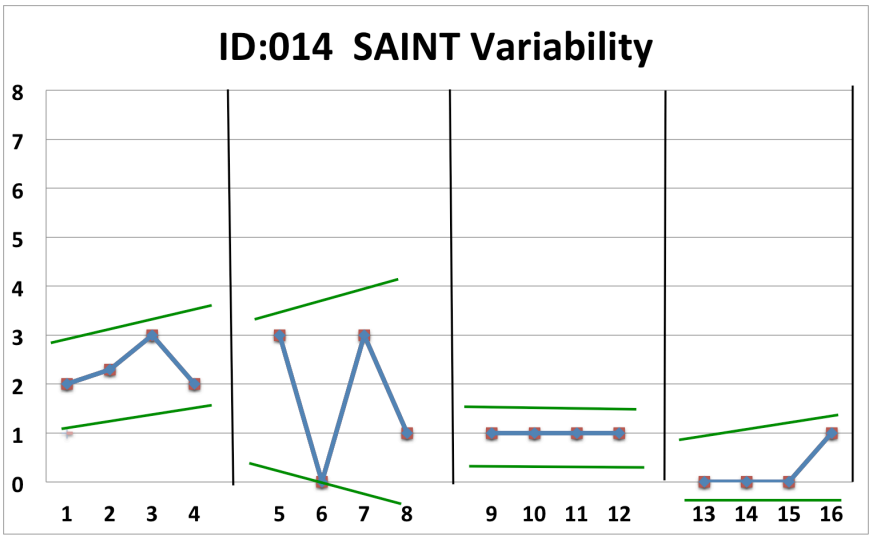
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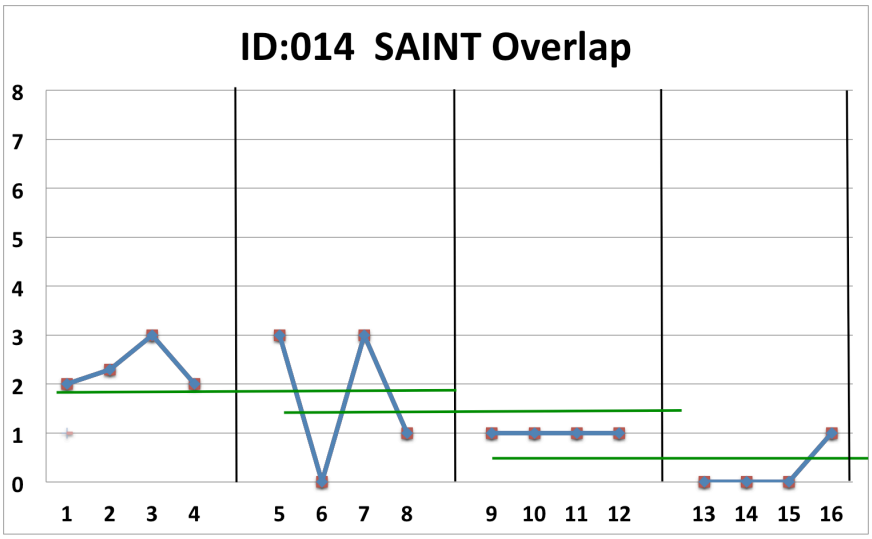
ID:014 SAINT Overlap
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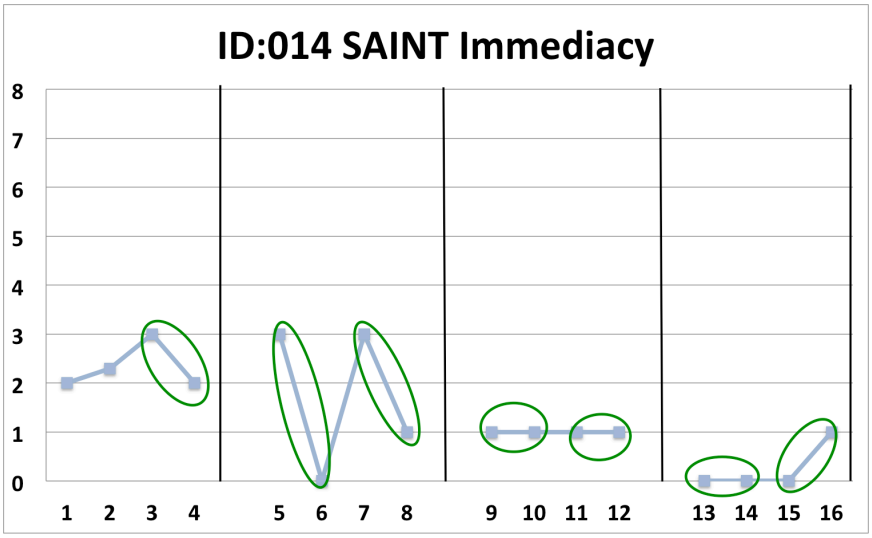
ID:014 SAINT Immediacy
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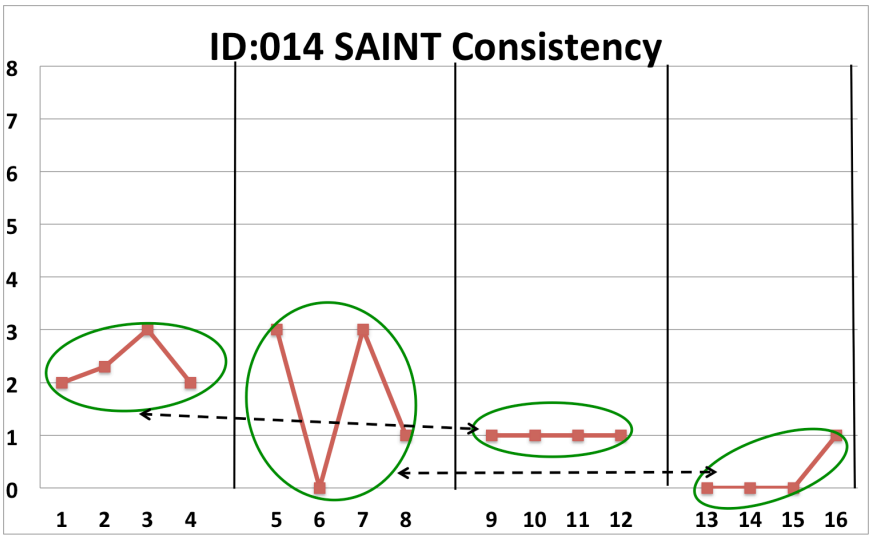
ID:014 SAINT Consistency
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0
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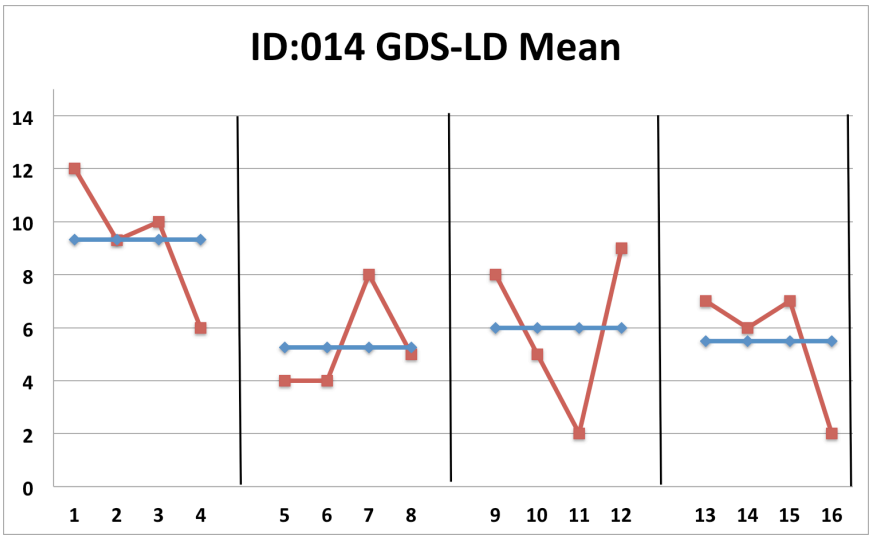
ID:014 GDS-LD Mean
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12
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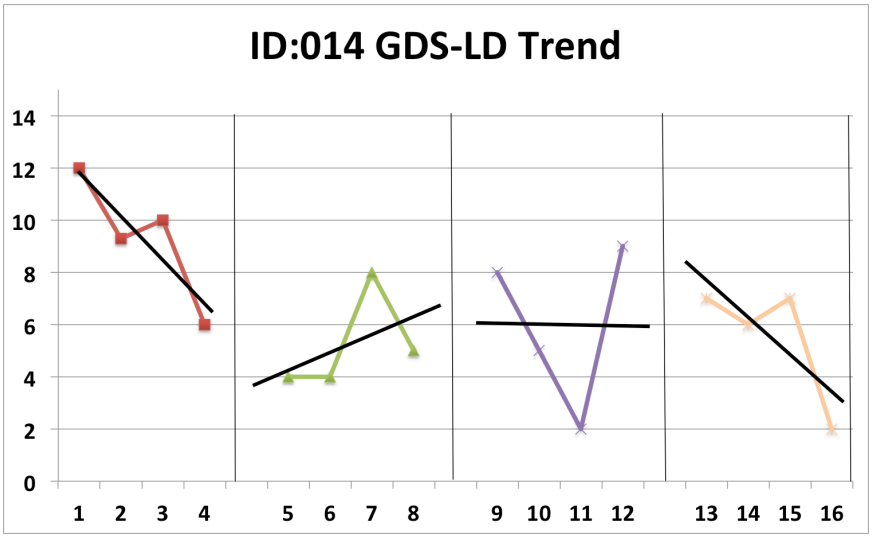
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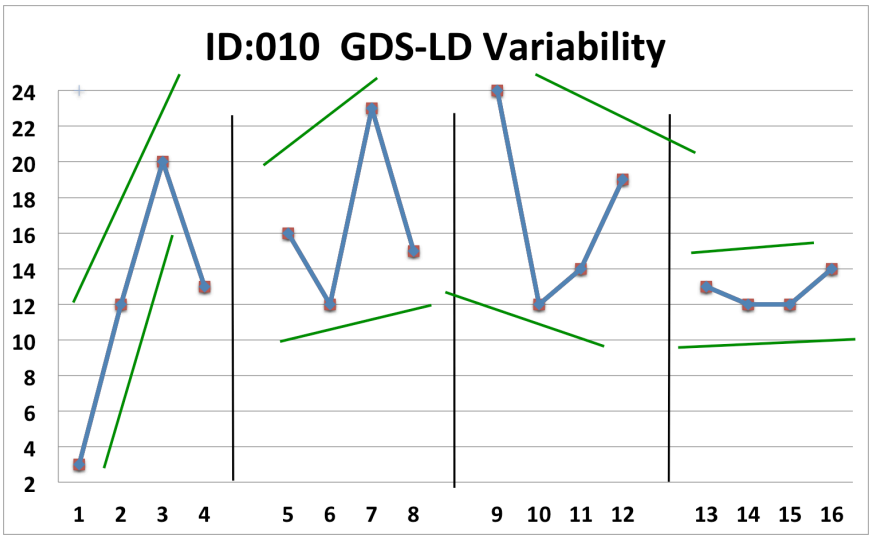
ID:010 GDS-LD Variability
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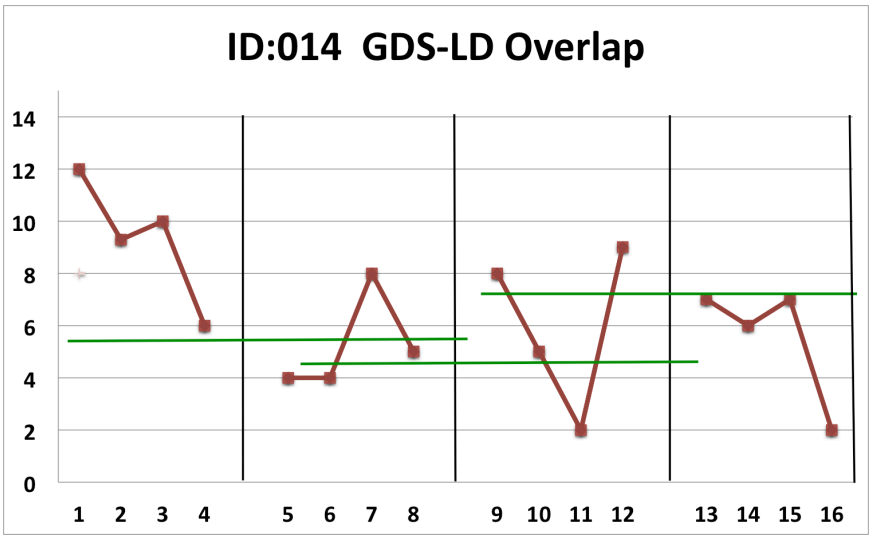
ID:014 GDS-LD Overlap
14
12
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8
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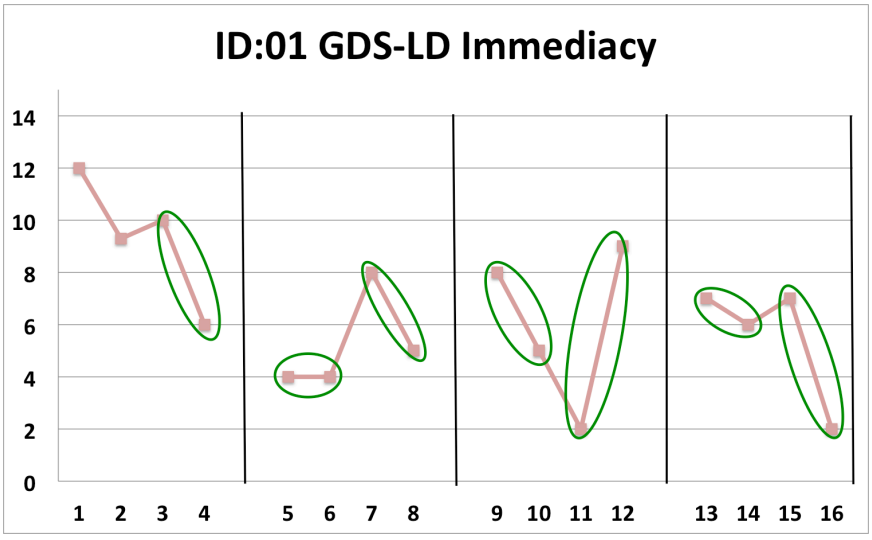
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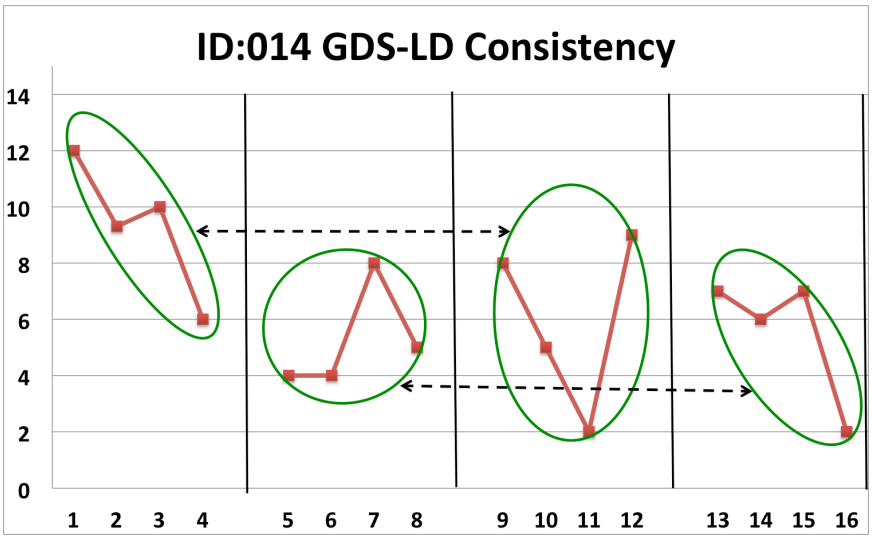
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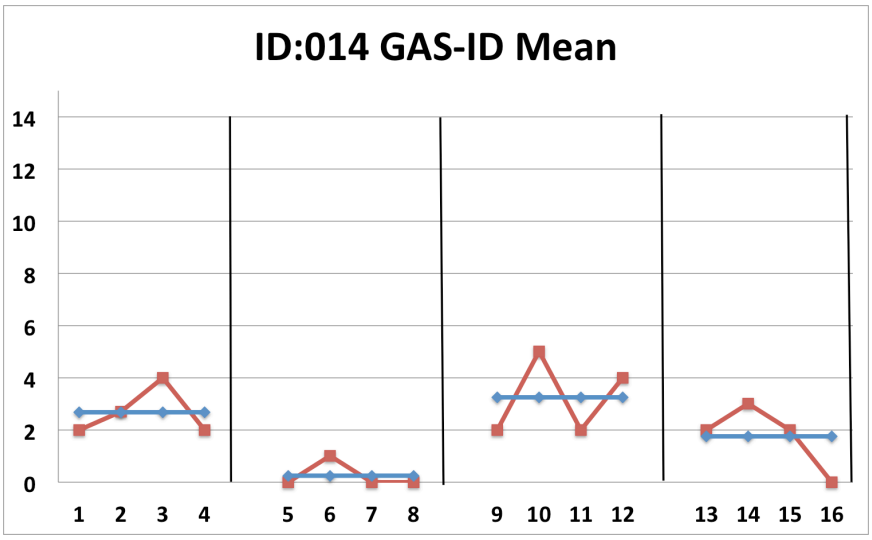
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8
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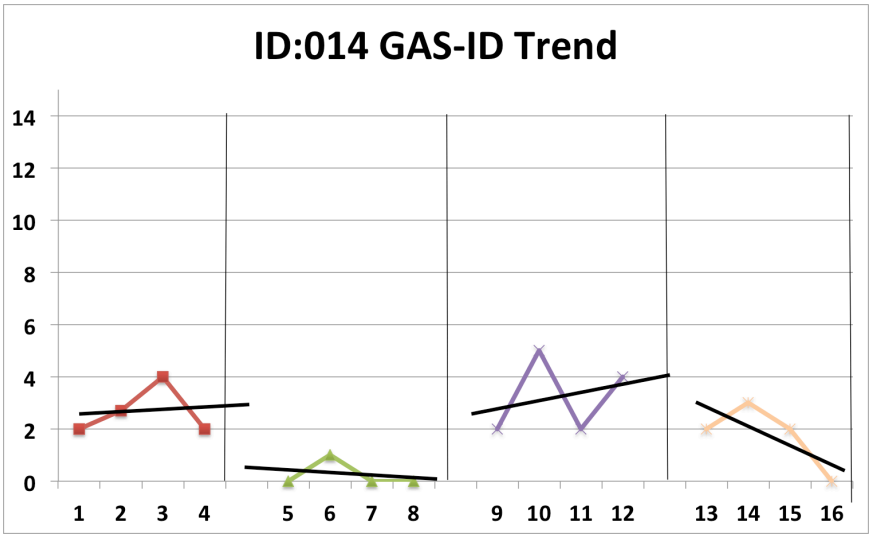
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16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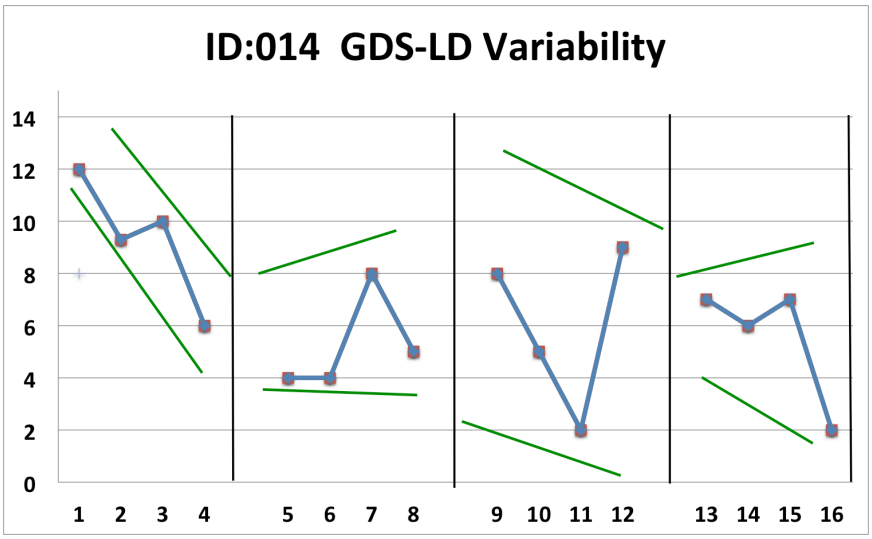
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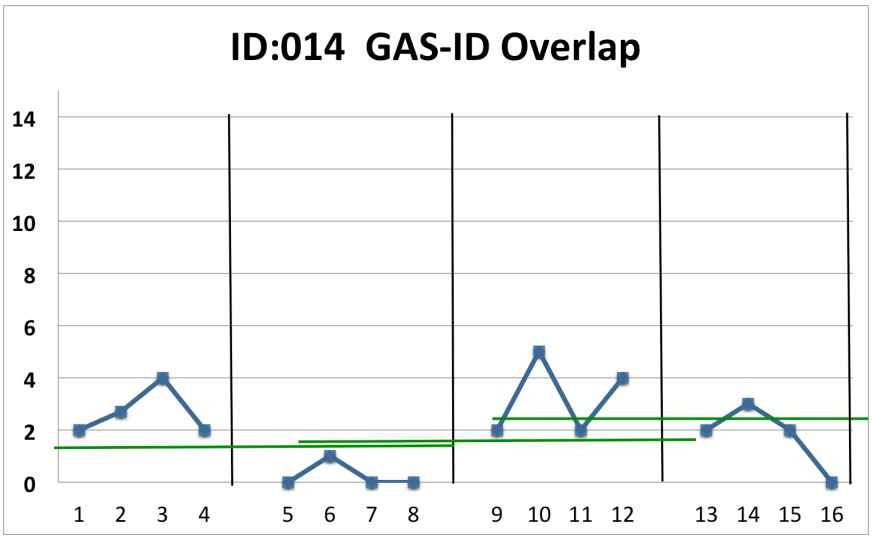
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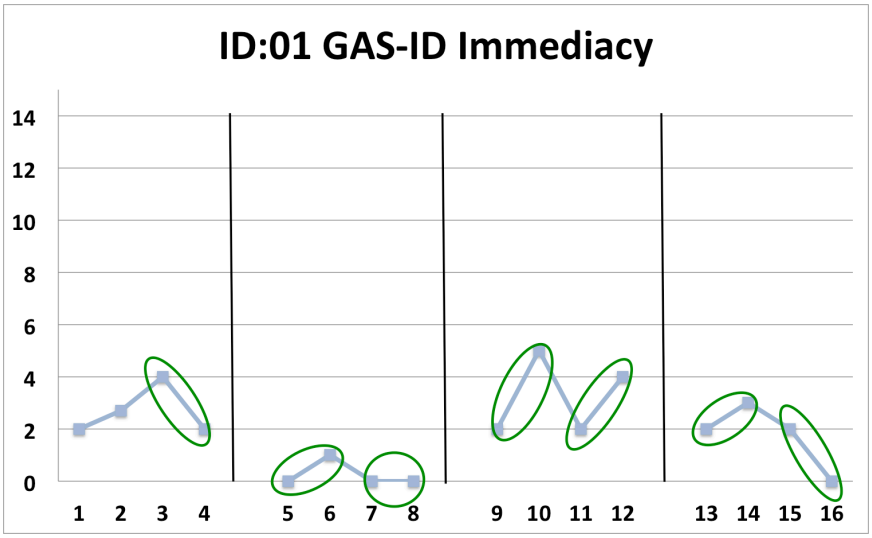
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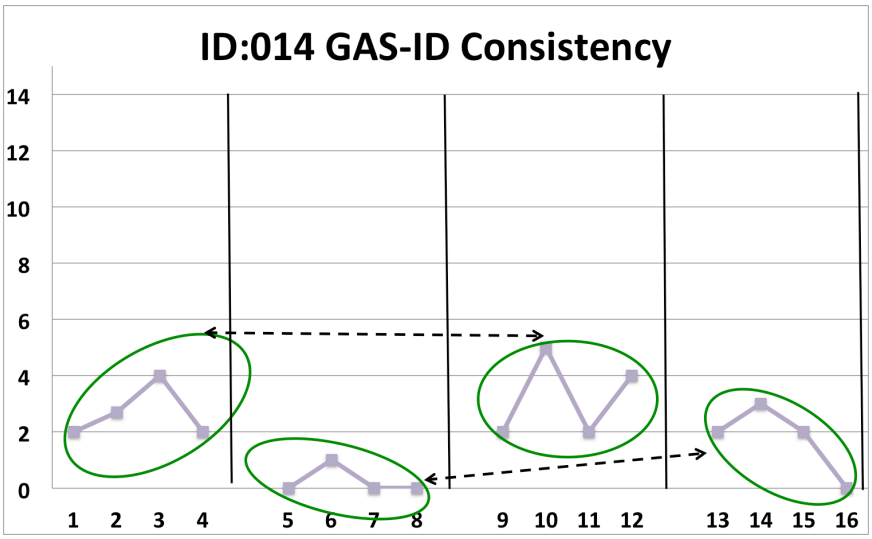
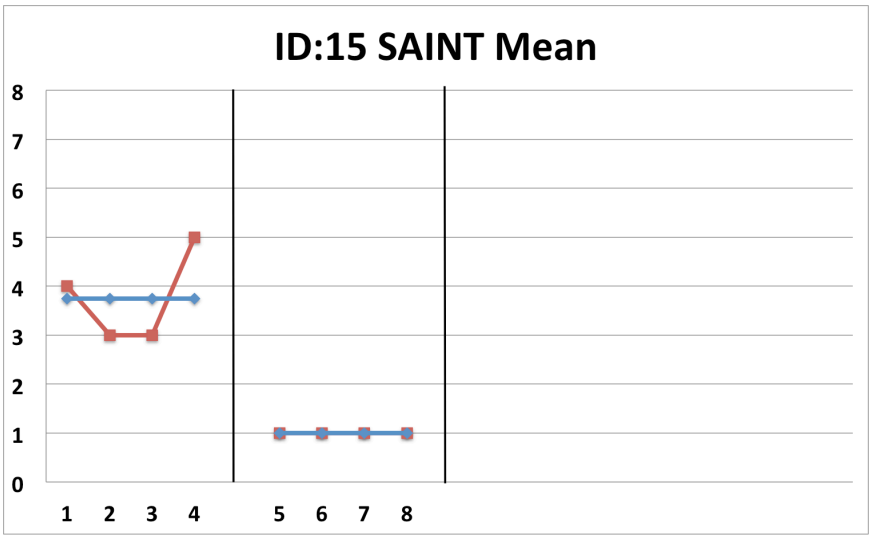

ID:014 GAS-ID Consistency
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

ID-15 WEEKLY SCORES AND VISUAL ANALYSIS

	SAINT	GDS-LD	GAS-ID
1	4	15	8
2	3	13	9
3	3	9	8
4	5	11	6
5	1	12	7
6	1	6	4
7	**1**	**9**	**5.5**
8	4	15	8
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**
X	**X**	**X**	**X**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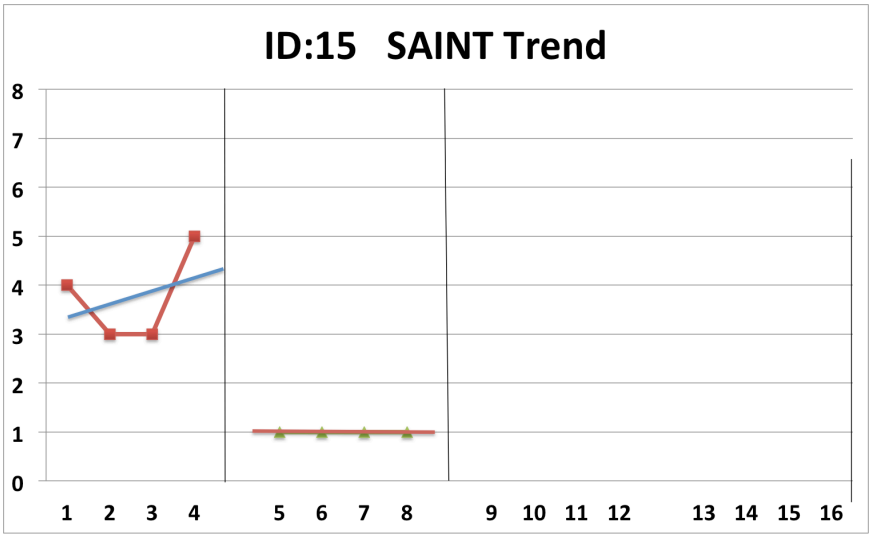
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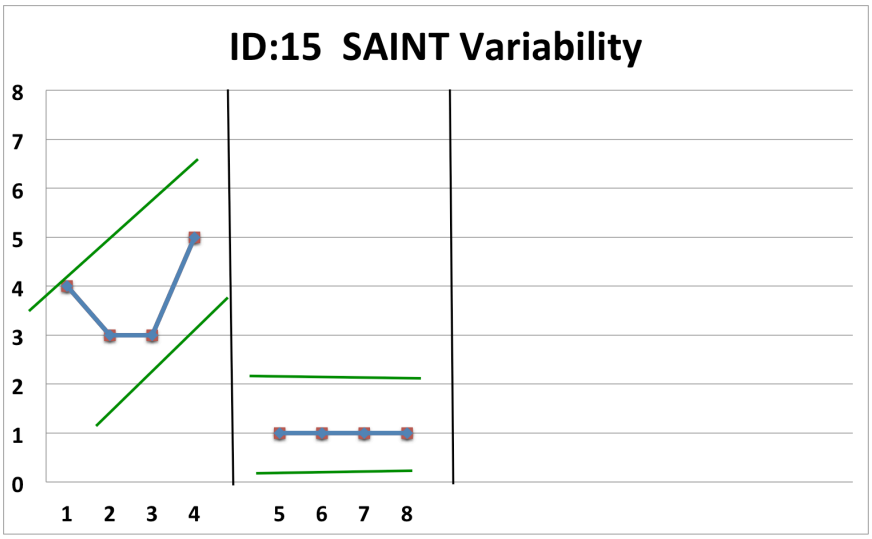
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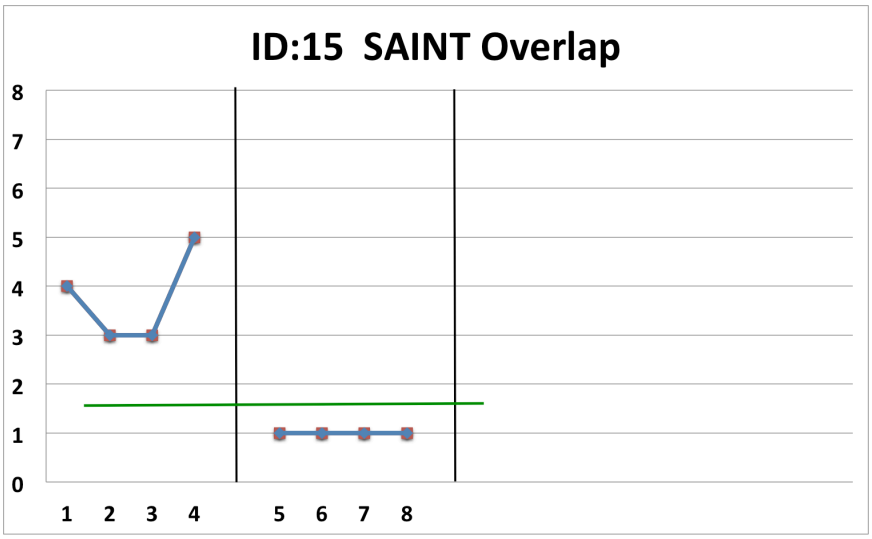
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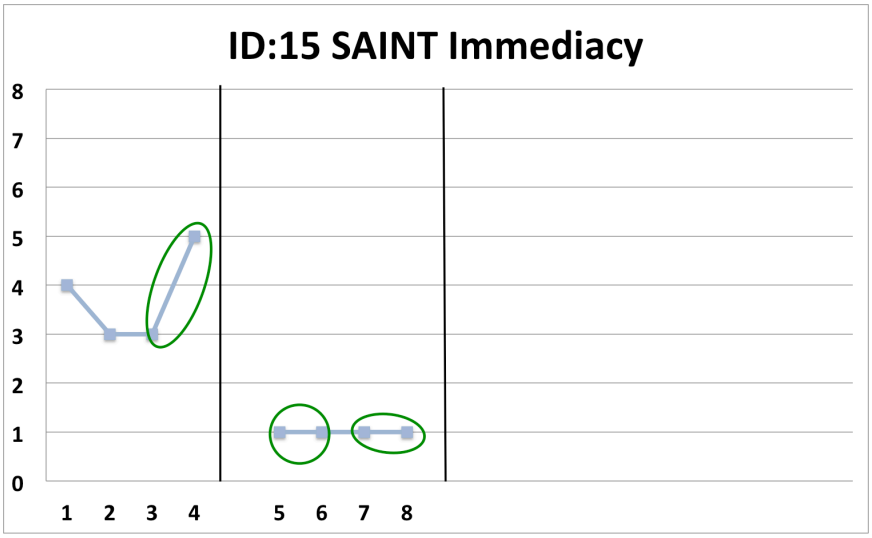
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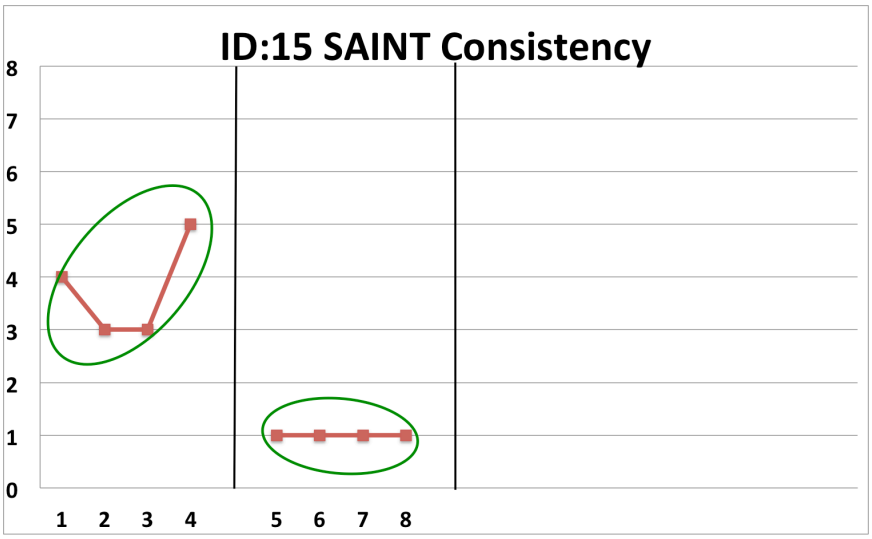
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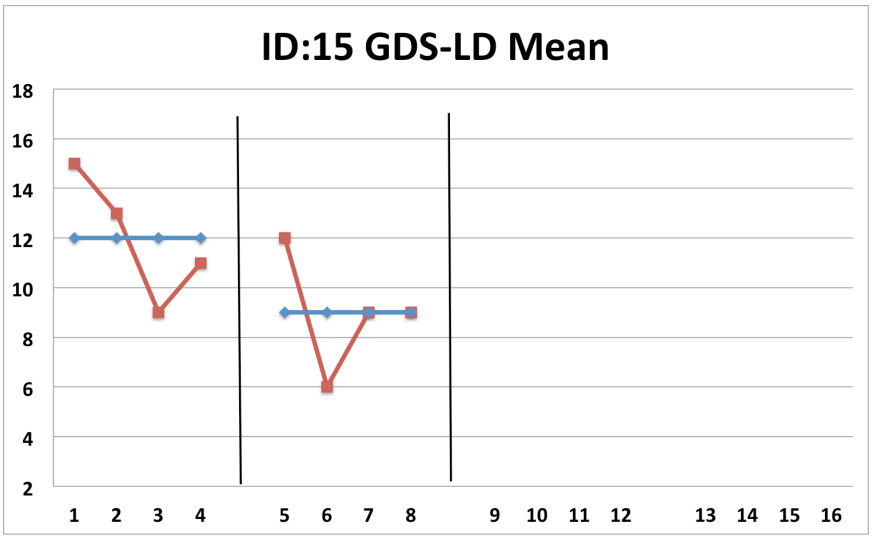
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18
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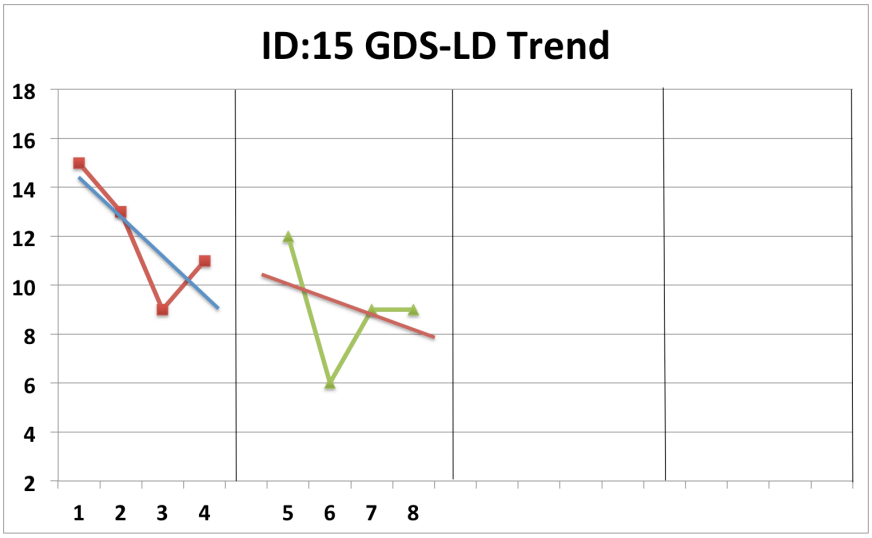
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16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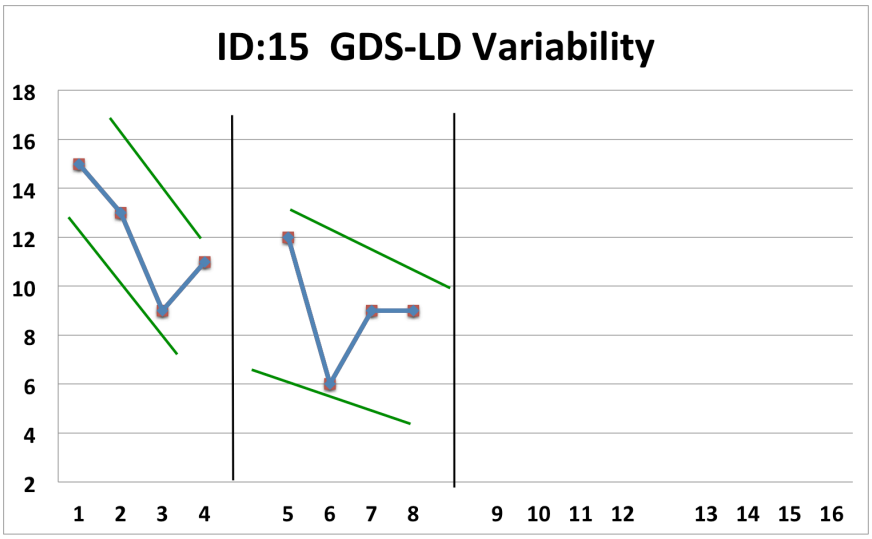
1 2 3 4 5 6 7 8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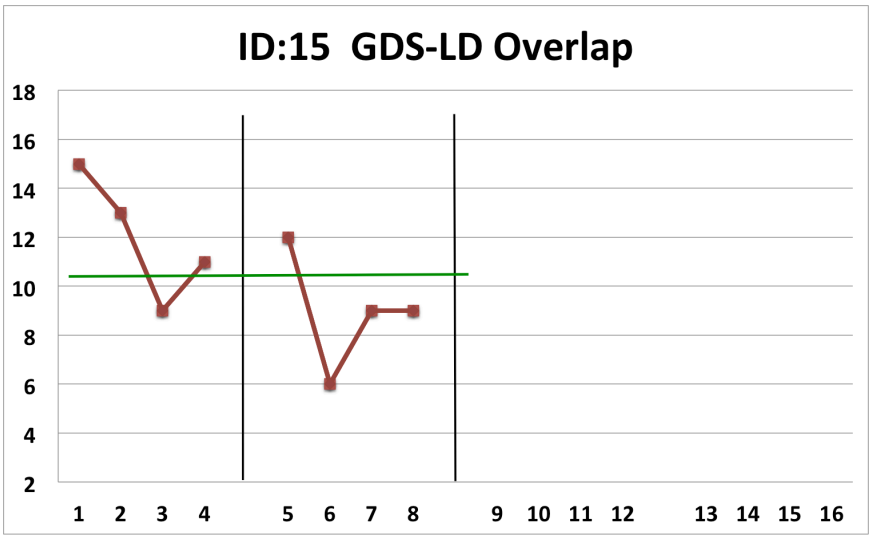
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16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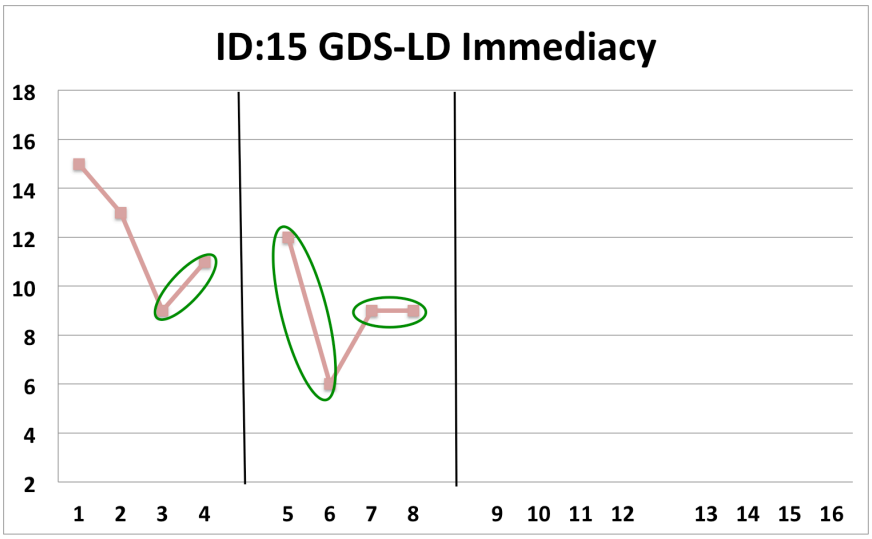
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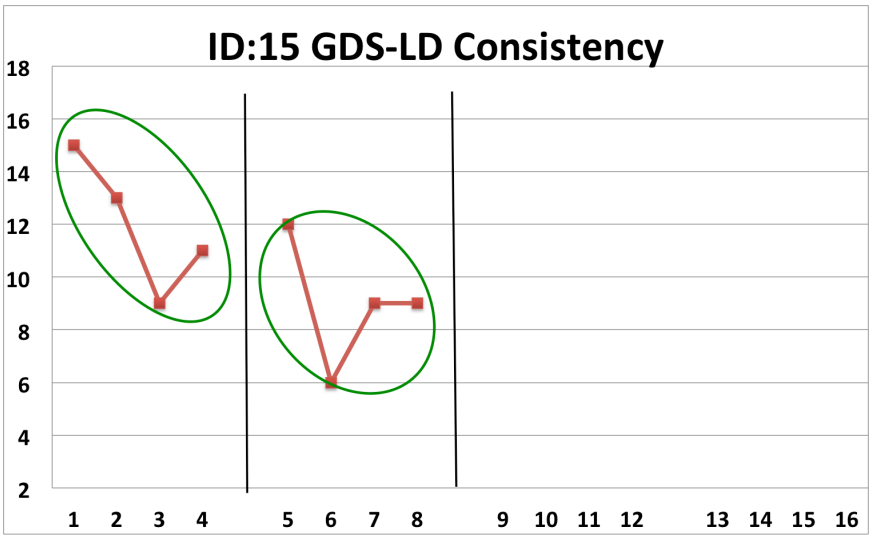
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16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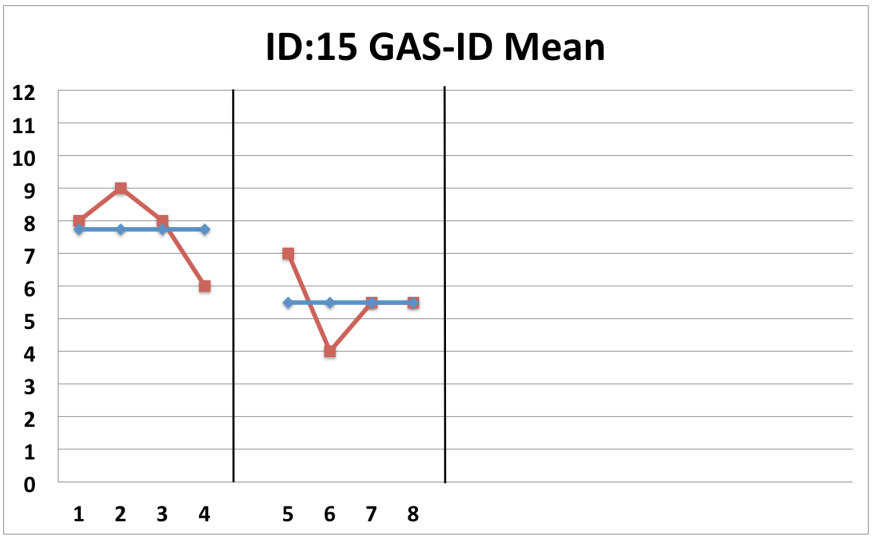
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16


ID:15 GAS-ID Mean
12
11
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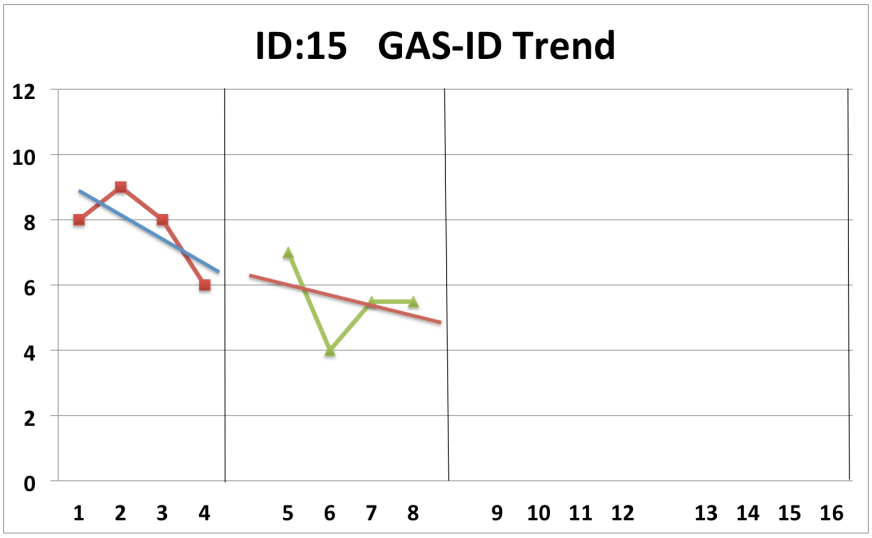
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8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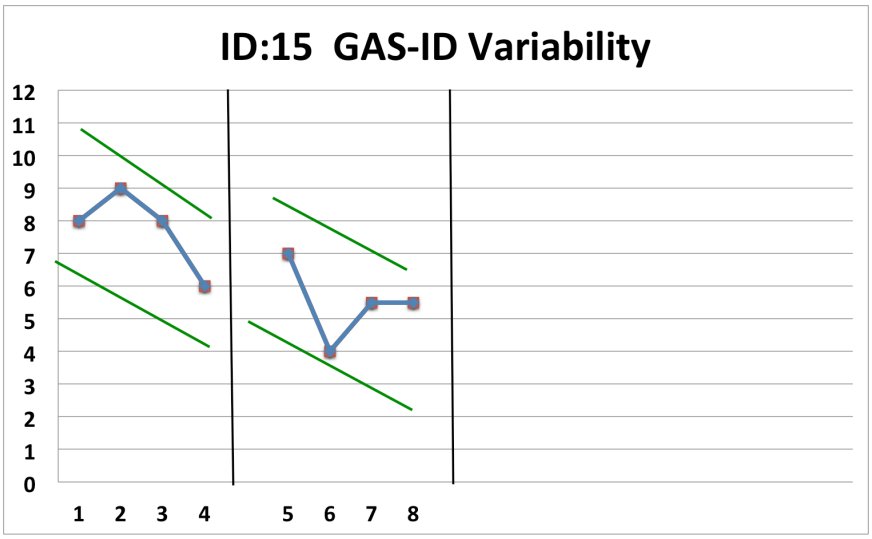
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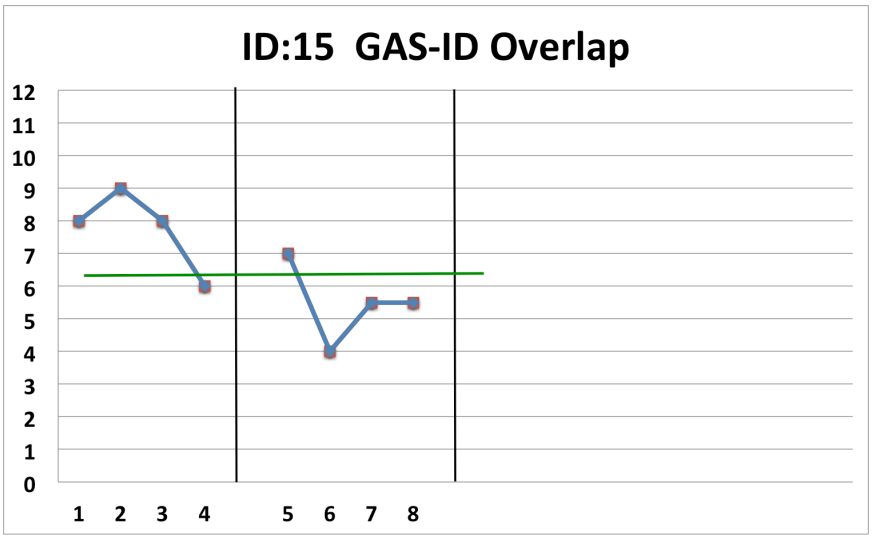
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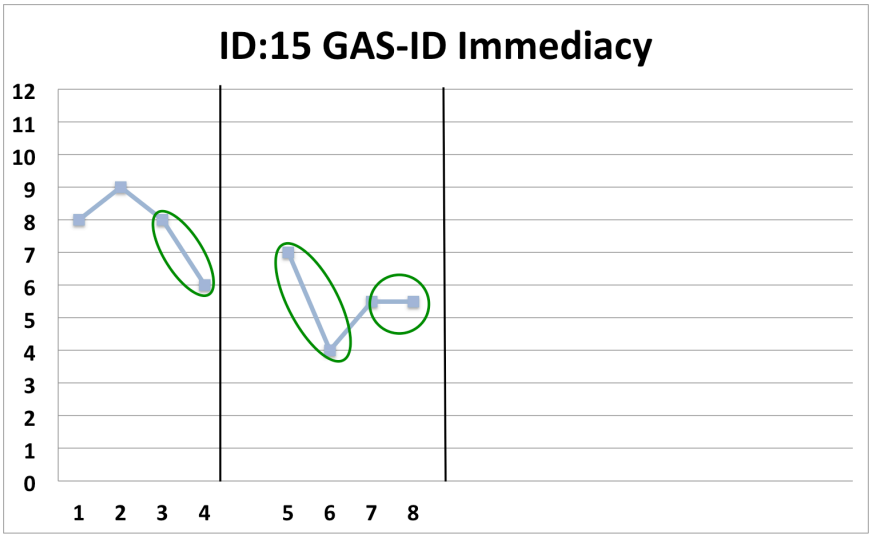
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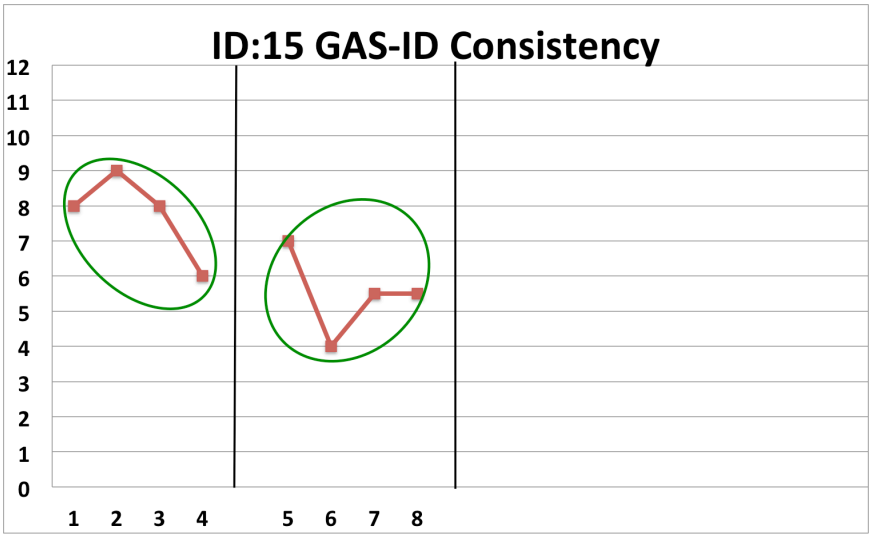
ID:15 GAS-ID Consistency
12
11
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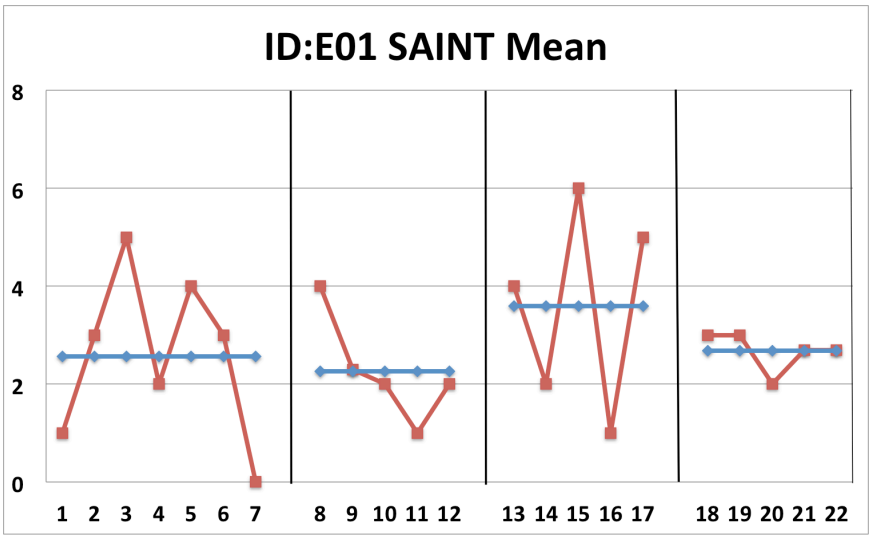
9
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8

PART 2 SCED

ID-E01 WEEKLY SCORES AND VISUAL ANALYSIS

Week	SAINT	GDS-LD	GAS-ID
1	1	4	6
2	3	6	8
3	5	5	4
4	2	2	7
5	4	5	6
6	3	5	2
7	0	0	1
8	4	8	4
9	**2.3**	**4**	**4.3**
10	2	2	7
11	1	2	2
12	2	2	1
13	4	6	3
14	2	2	4
15	6	13	10
16	1	0	2
17	5	10	7
18	3	3	2
19	3	3	1
20	2	5	3
21	**2.7**	**3.7**	**2**
22	**2.7**	**3.7**	**2**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8
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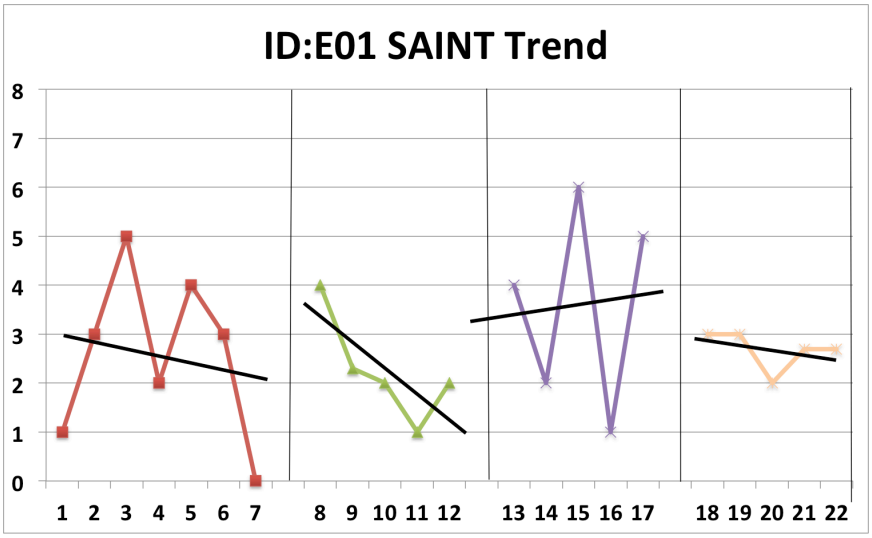
ID:E01 SAINT Trend
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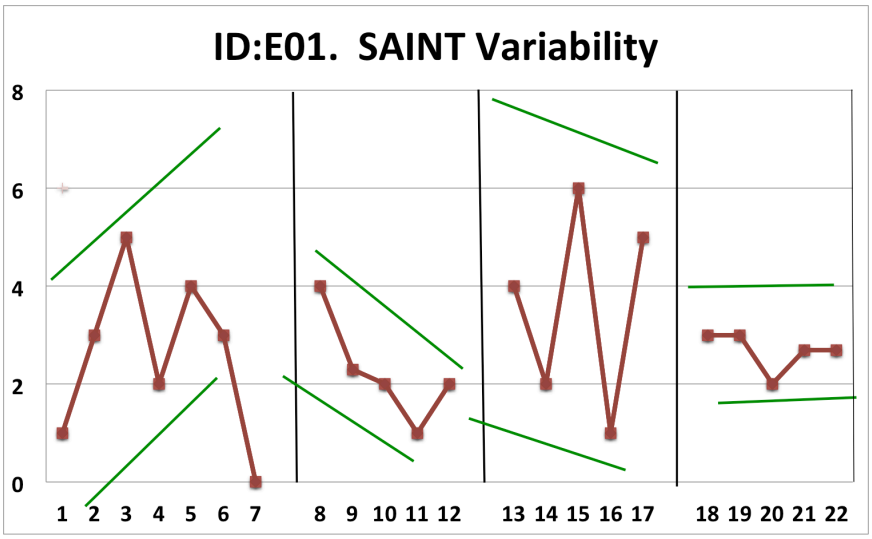
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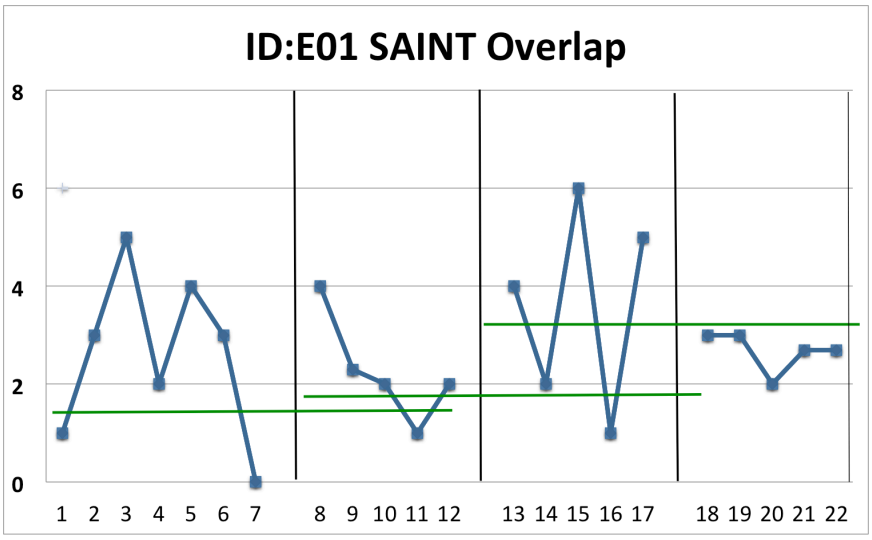
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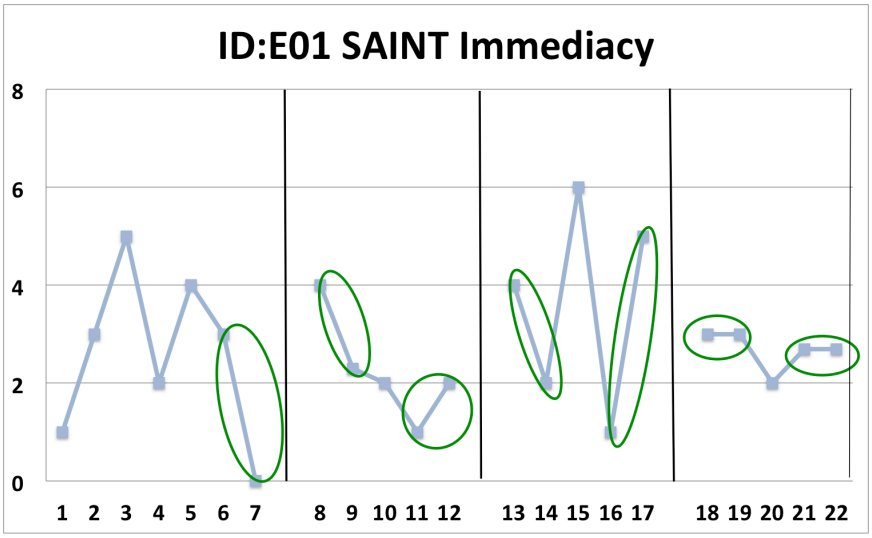
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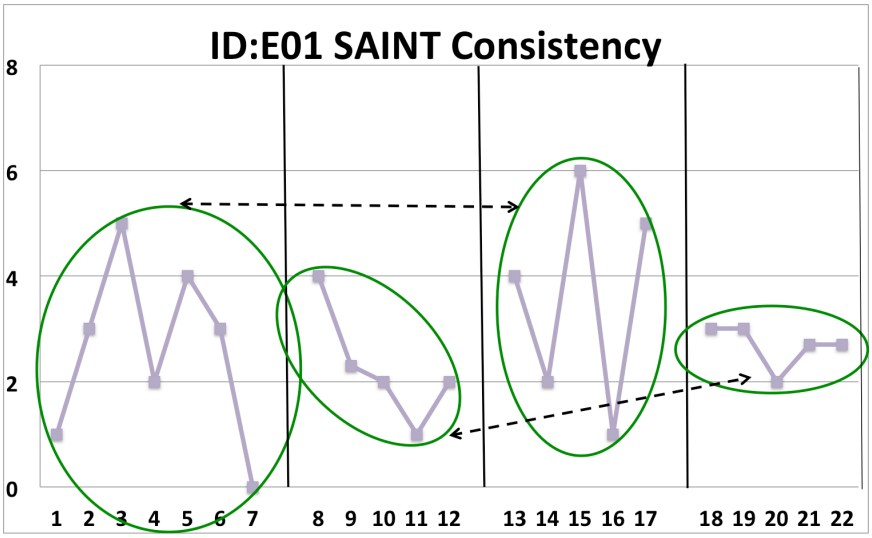
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2
0
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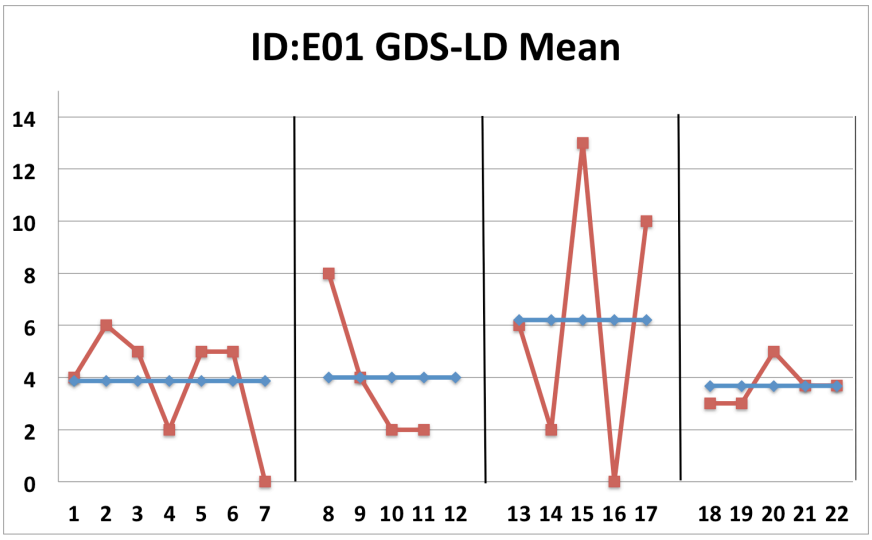
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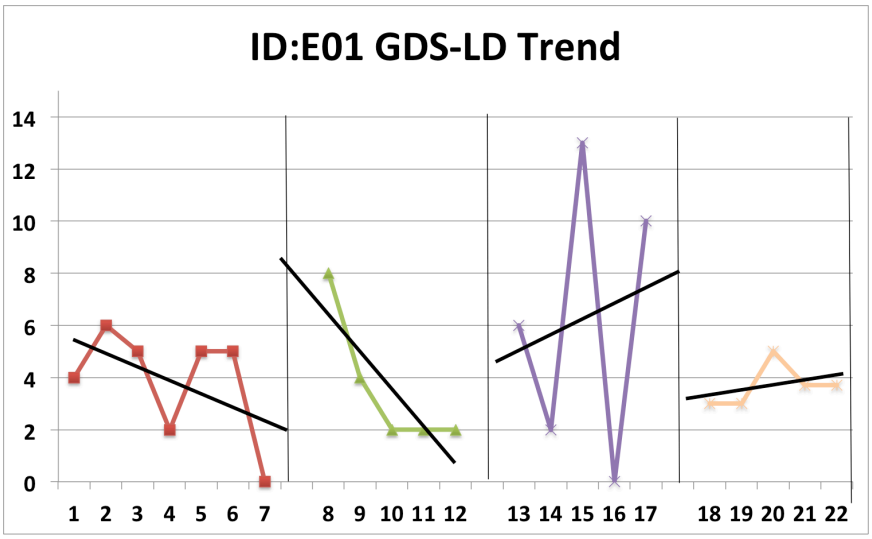
13 14 15 16 17
18 19 20 21 22


ID:E01 GDS-LD Trend
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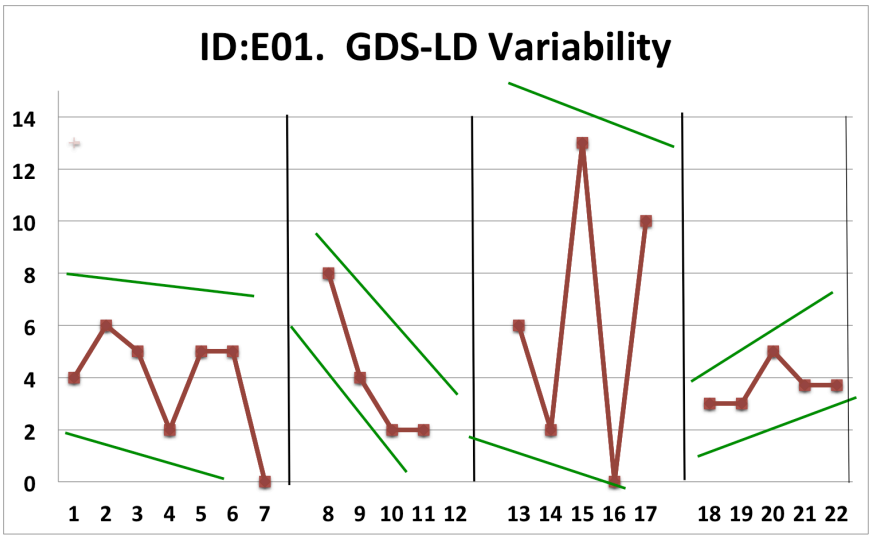
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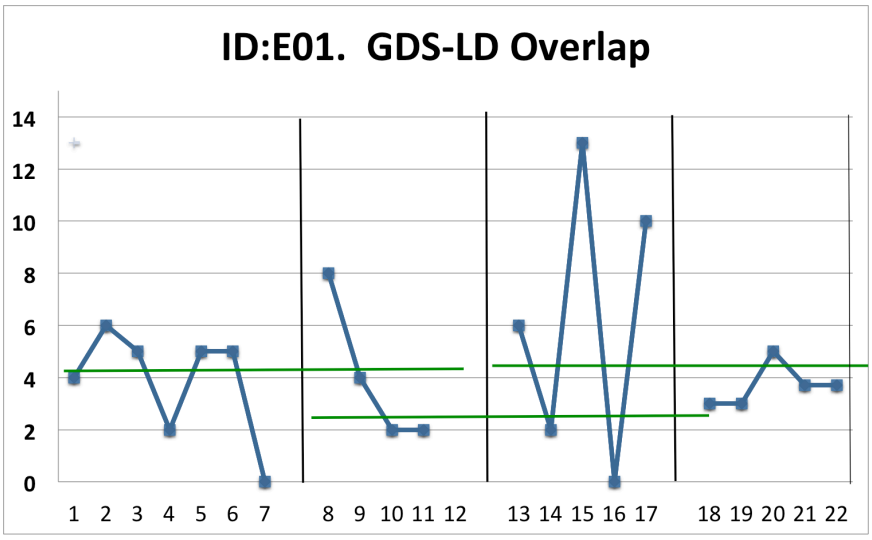
18 19 20 21 22


ID:E01. GDS-LD Overlap
14
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10
8
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4
2
0
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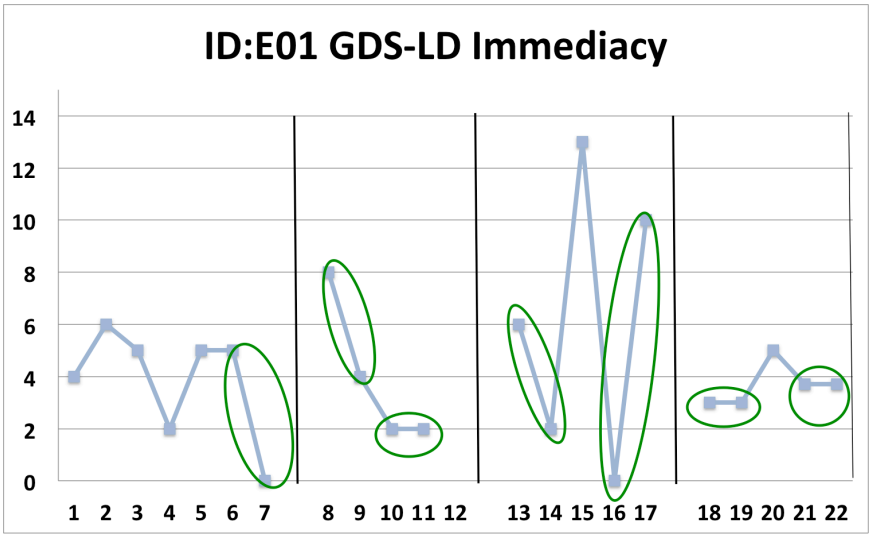
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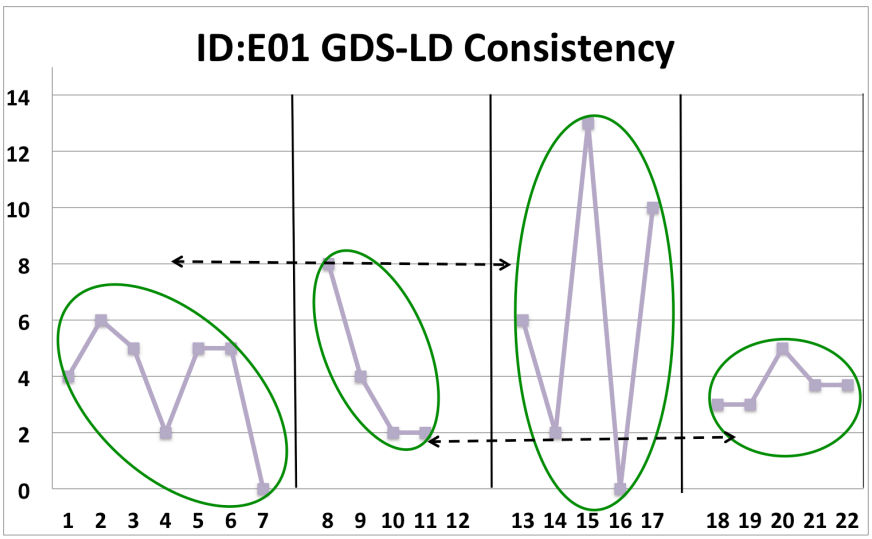
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0
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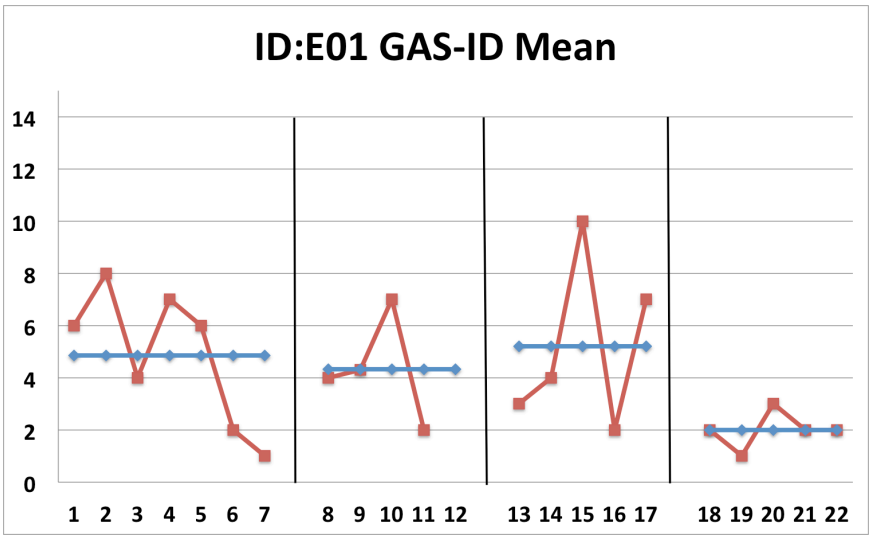
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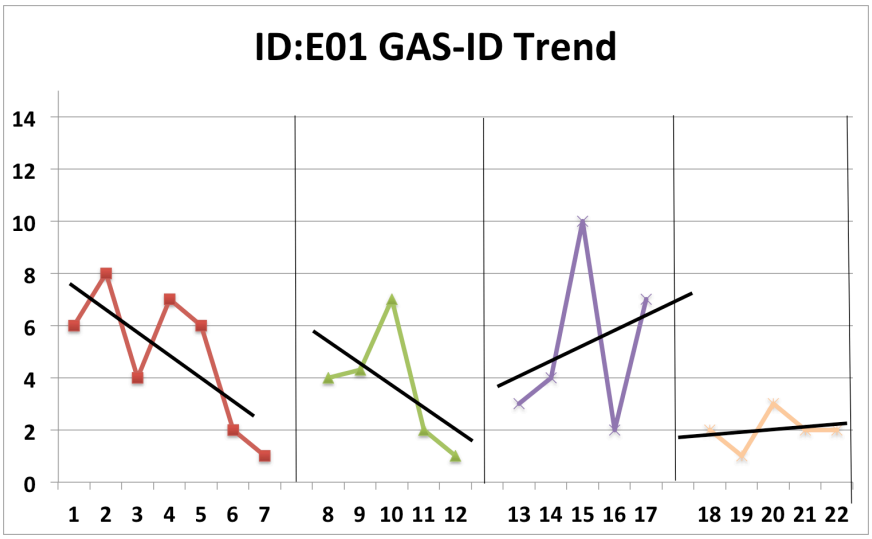
18 19 20 21 22


ID:E01 GAS-ID Trend
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1 2 3 4 5 6 7
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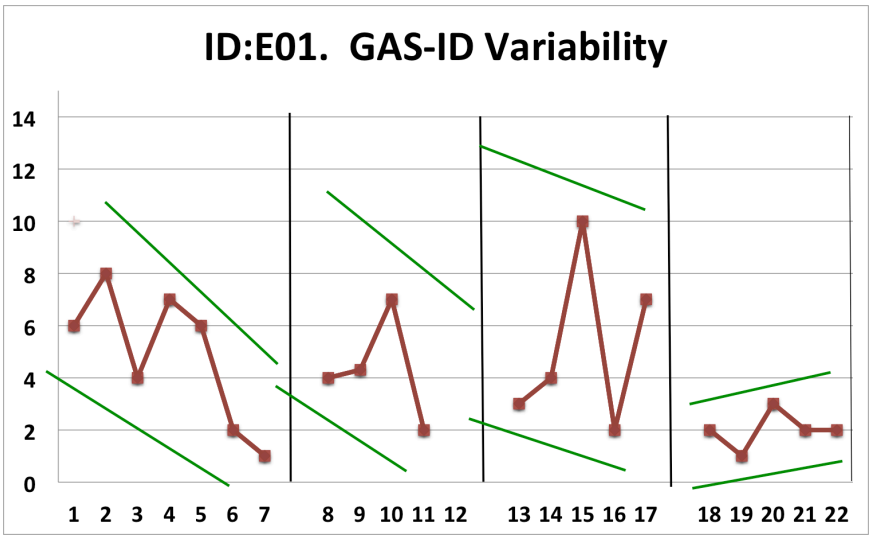
ID:E01. GAS-ID Variability
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12
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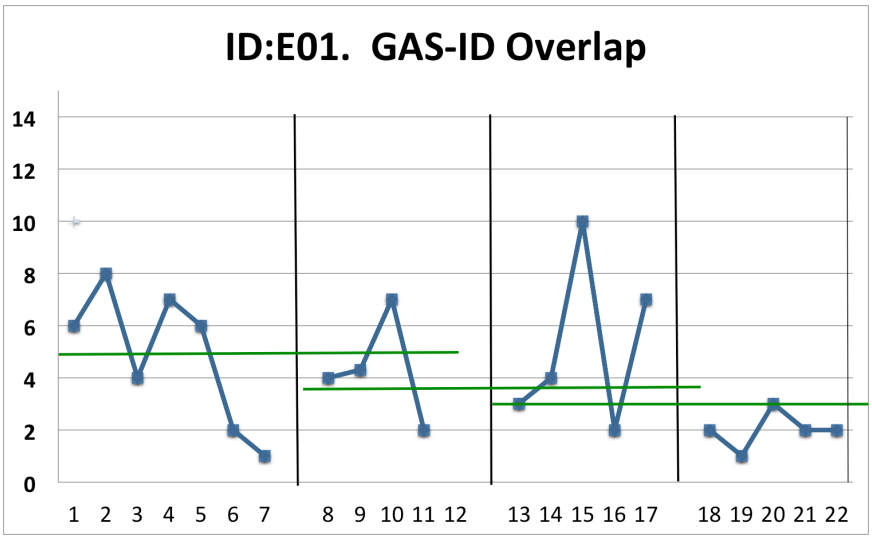
ID:E01. GAS-ID Overlap
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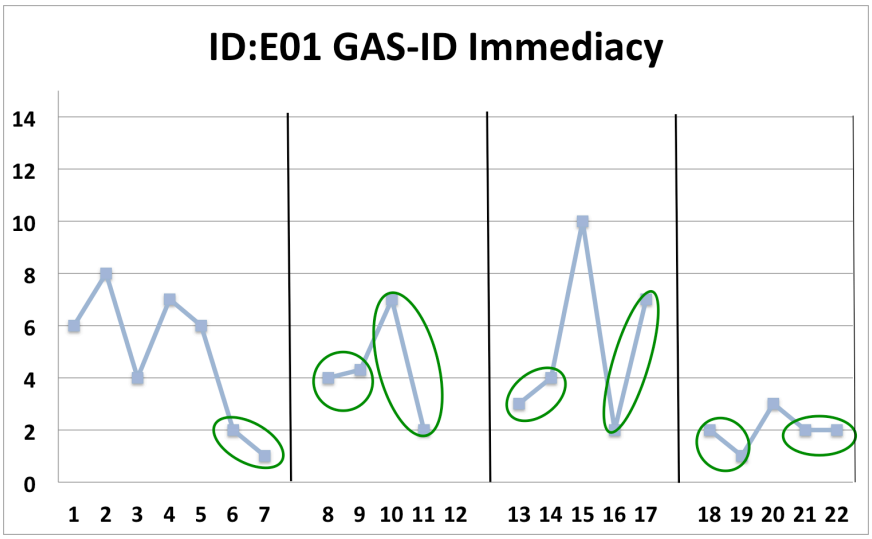
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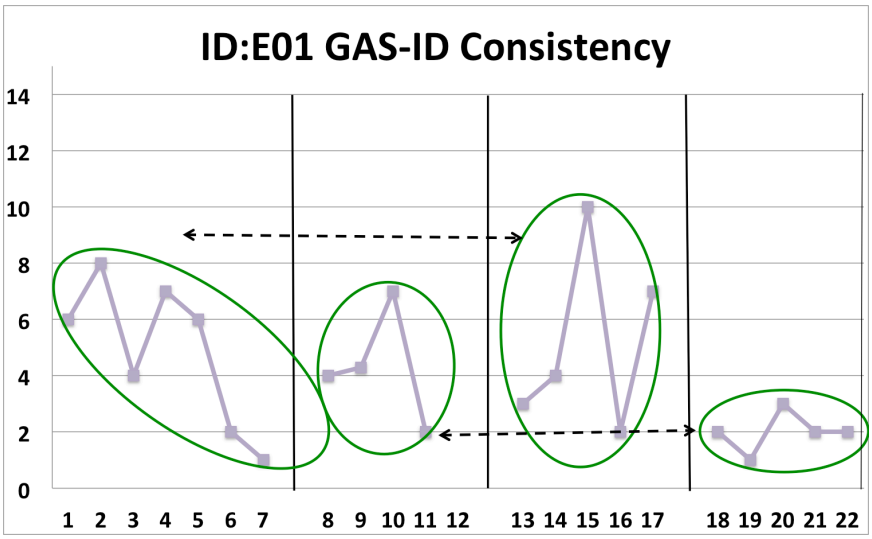
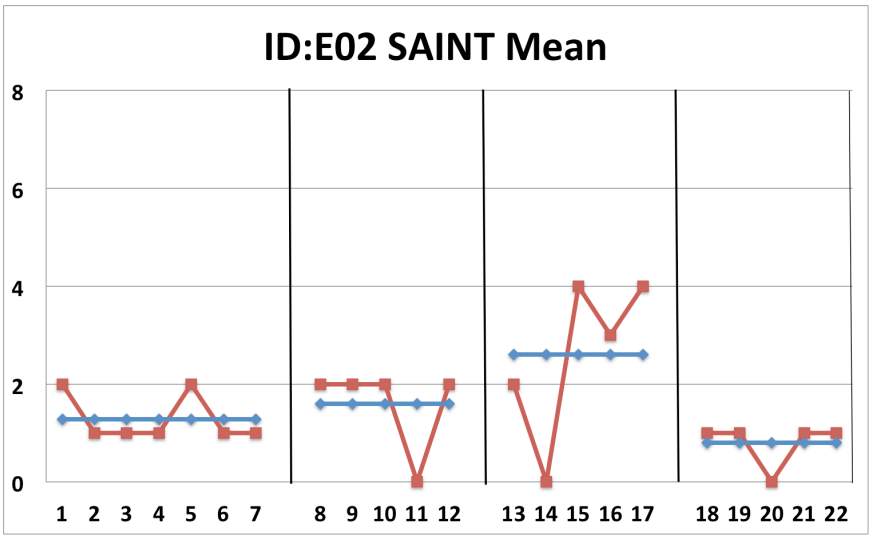

ID:E01 GAS-ID Consistency
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7
8 9 10 11 12
13 14 15 16 17
18 19 20 21 22

ID-E02 WEEKLY SCORES AND VISUAL ANALYSIS

week	SAINT	GDS-LD	GAS-ID
1	2	5	1
2	1	4	1
3	1	3	0
4	1	4	3
5	2	4	2
6	1	3	2
7	1	5	1
8	2	4	2
9	2	4	1
10	2	1	0
11	0	2	0
12	2	3	0
13	2	5	2
14	0	4	3
15	4	9	3
16	3	5	2
17	4	10	8
18	1	3	1
19	1	4	2
20	0	1	0
21	1	3	1
22	1	3	0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8
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2
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1 2 3 4 5 6 7
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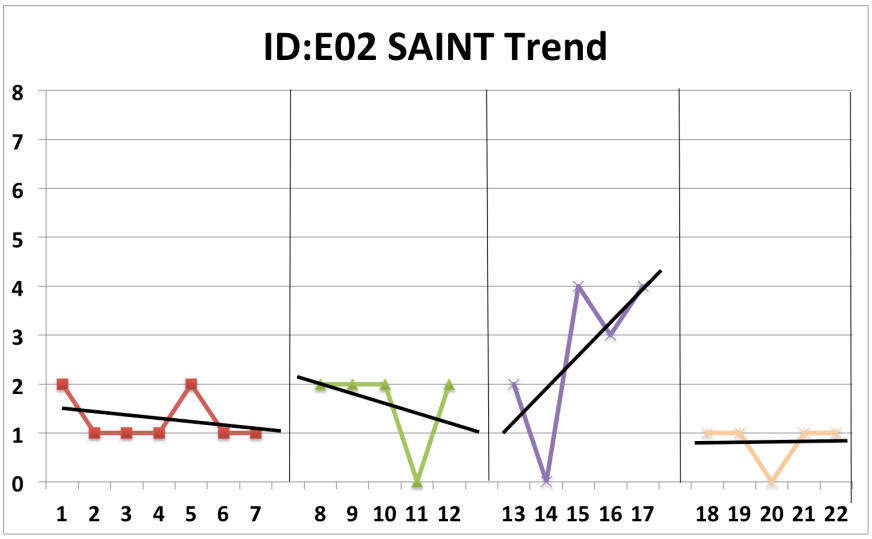
18 19 20 21 22


ID:E02 SAINT Trend
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4
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1 2 3 4 5 6 7
8 9 10 11 12
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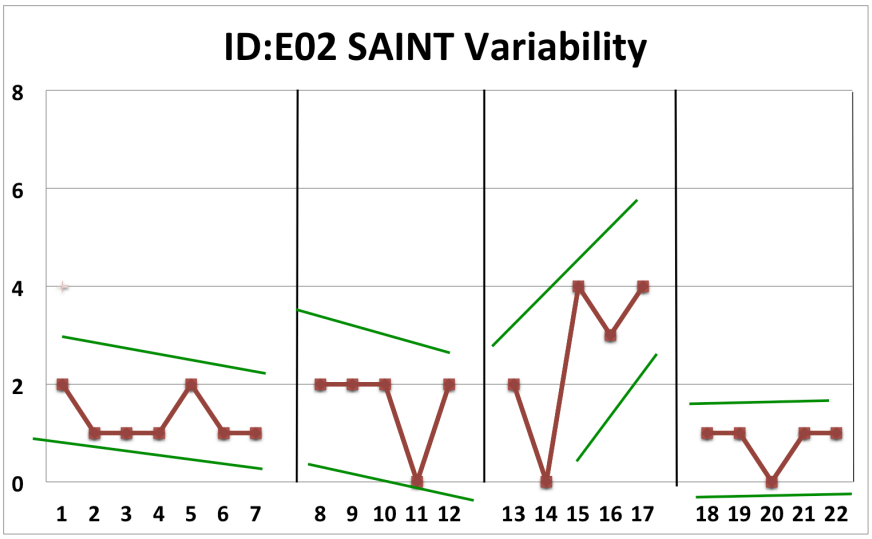
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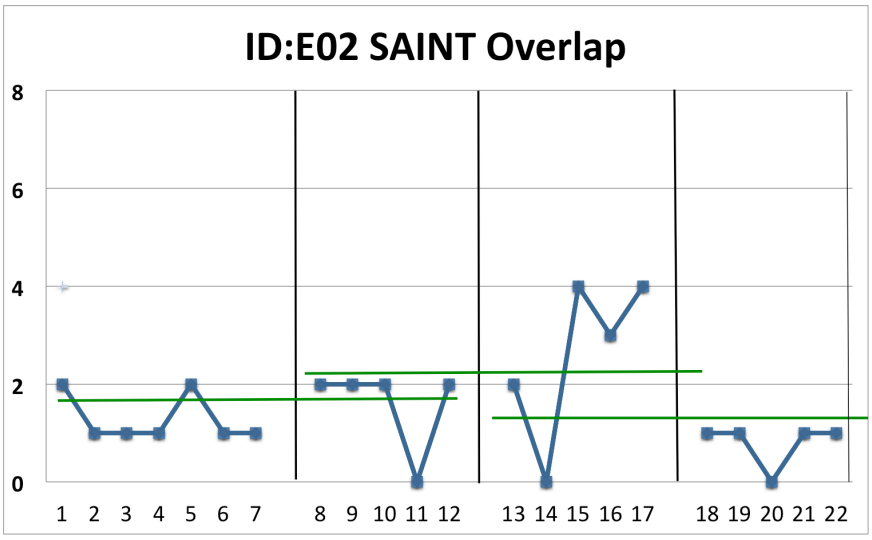
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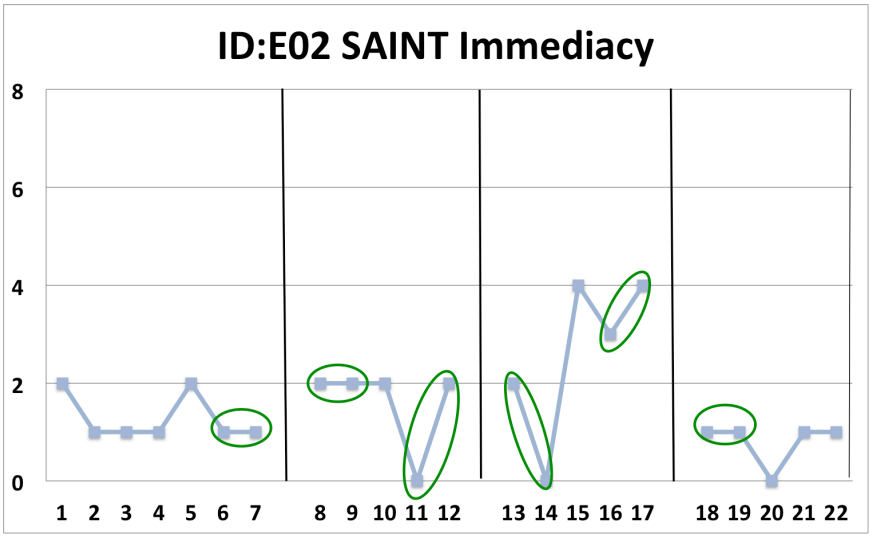
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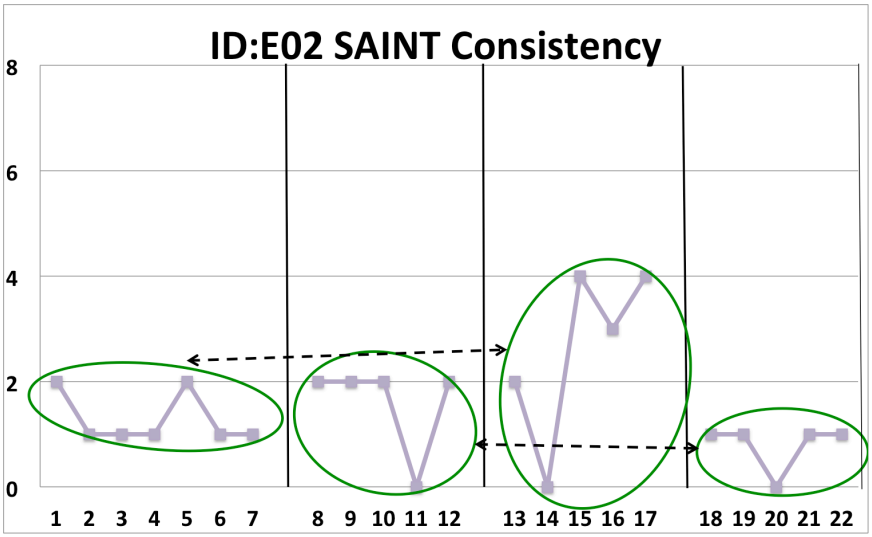
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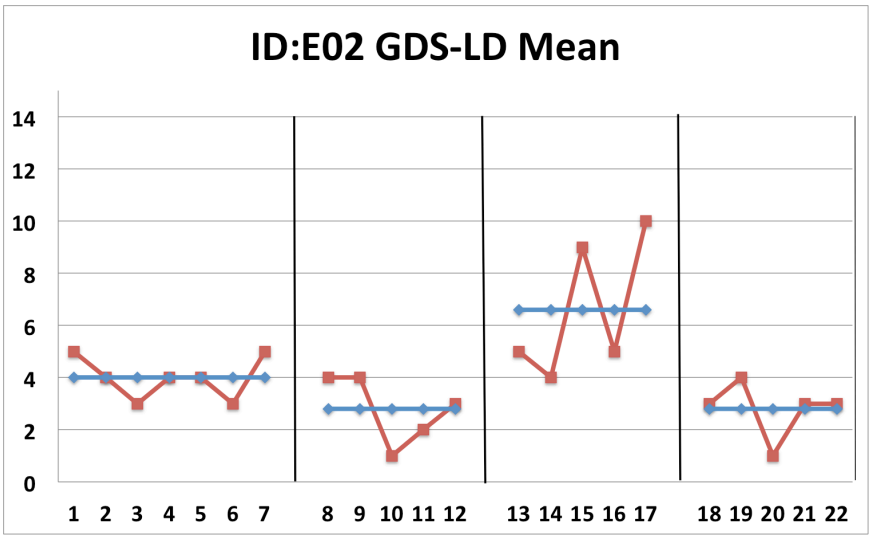
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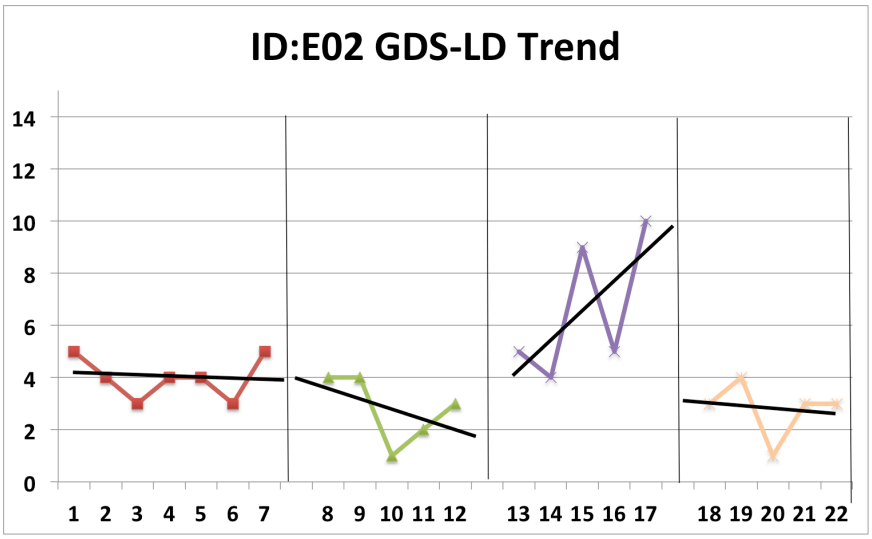
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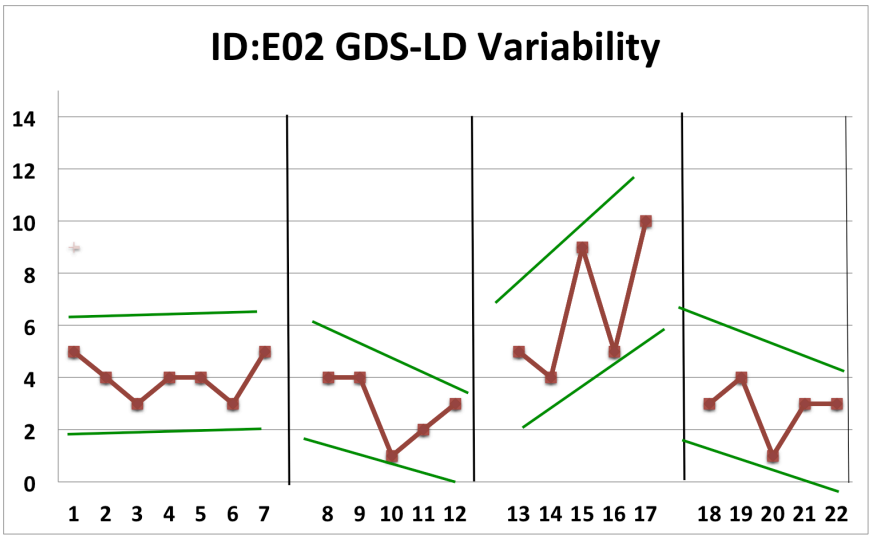
ID:E02 GDS-LD Variability
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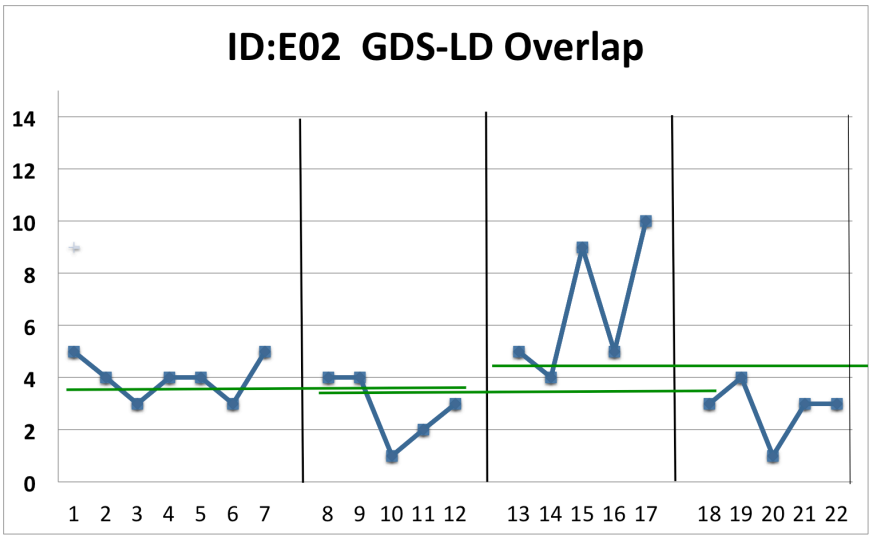
13 14 15 16 17
18 19 20 21 22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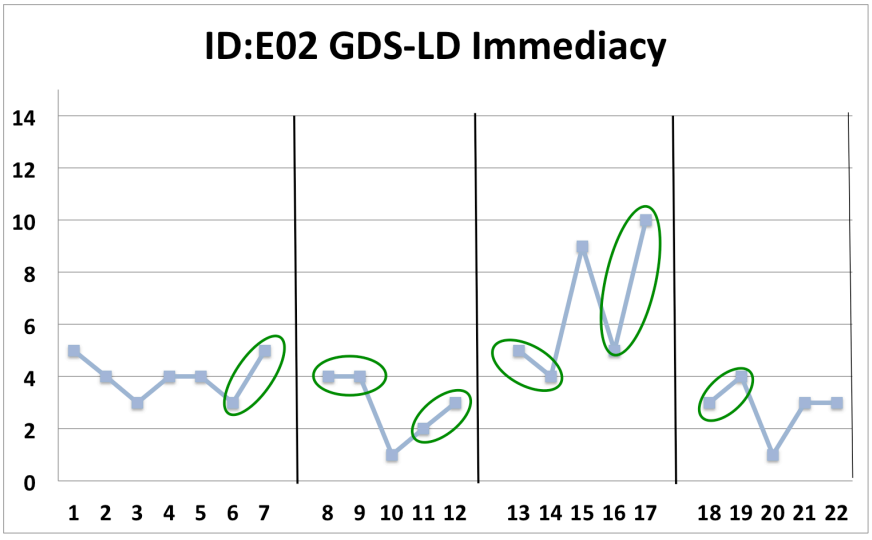
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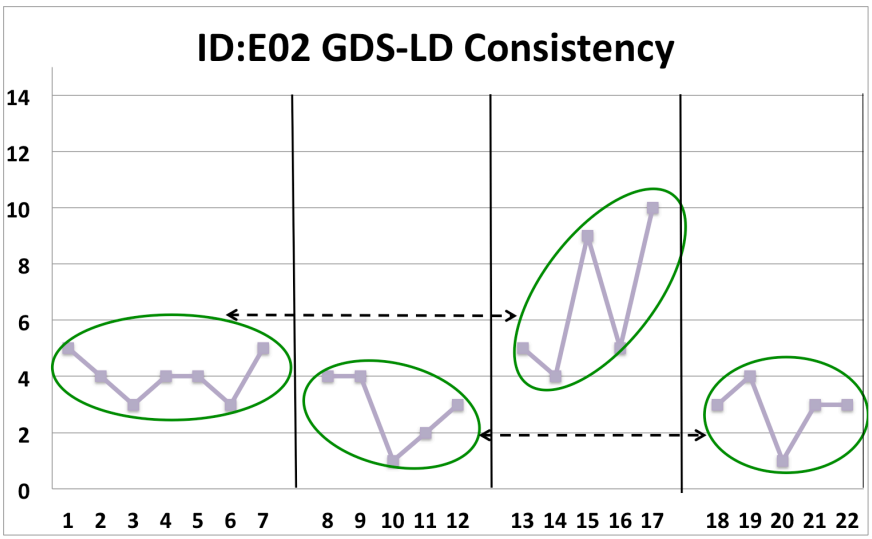
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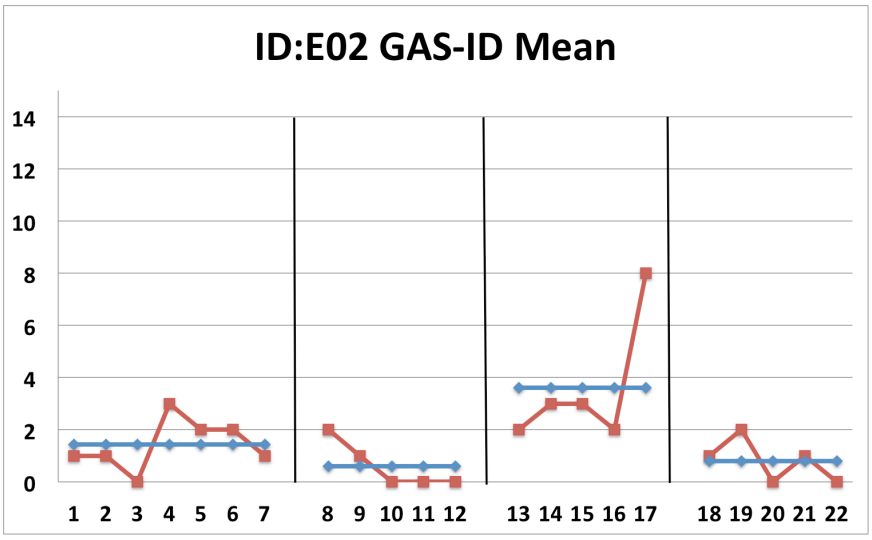
ID:E02 GAS-ID Mean
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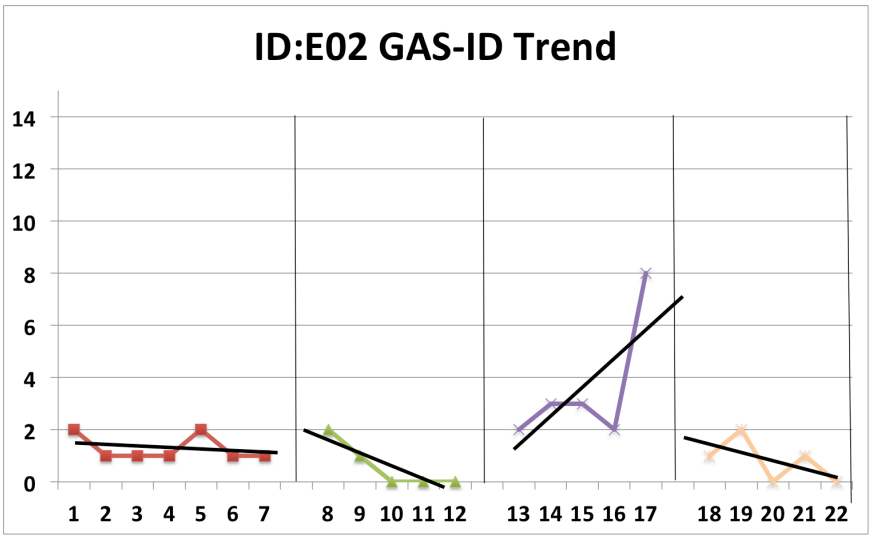
4
2
0
1 2 3 4 5 6 7
8 9 10 11 12
13 14 15 16 17
18 19 20 21 22


ID:E02 GAS-ID Trend
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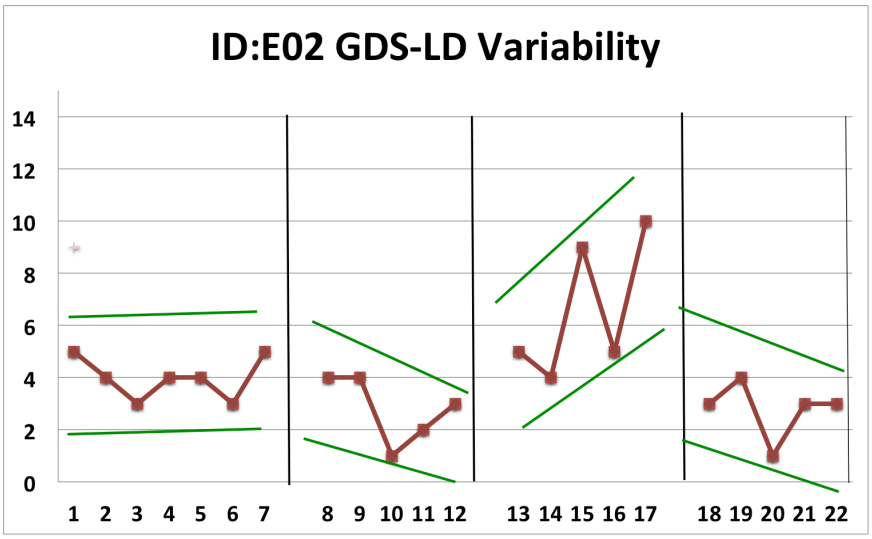
1 2 3 4 5 6 7
8 9 10 11 12
13 14 15 16 17
18 19 20 21 22


ID:E02 GDS-LD Variability
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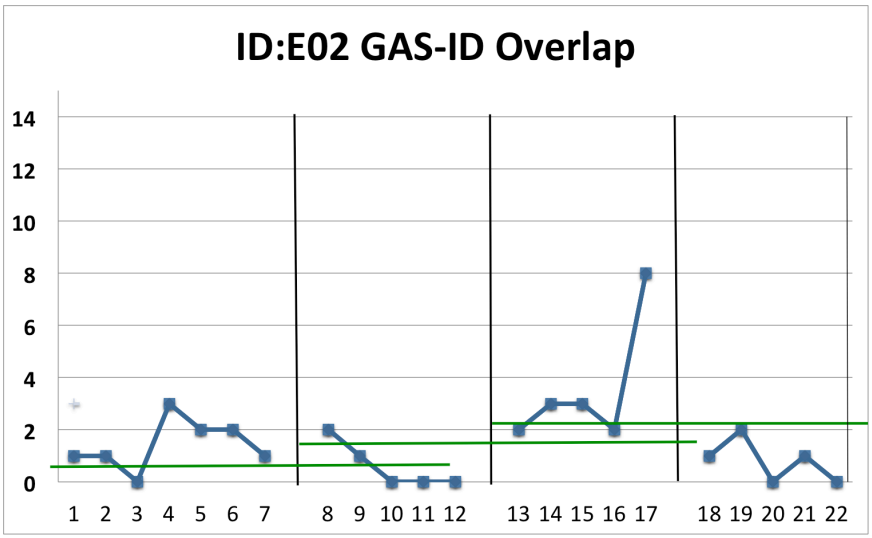
13 14 15 16 17
18 19 20 21 22


ID:E02 GAS-ID Overlap
14
12
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8
6
4
2
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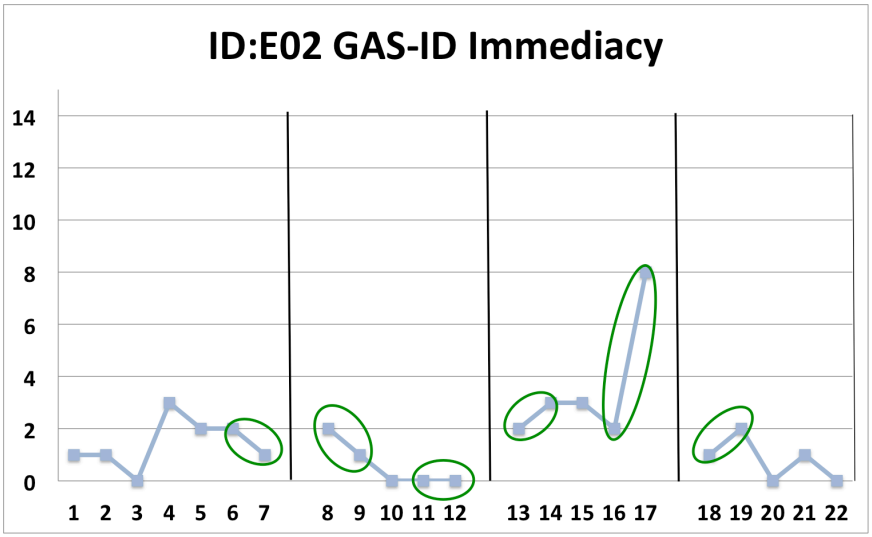
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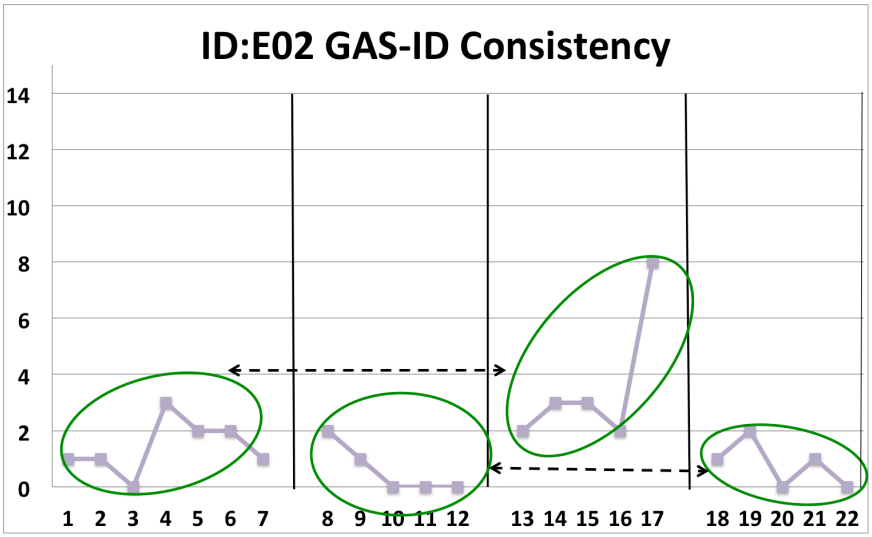
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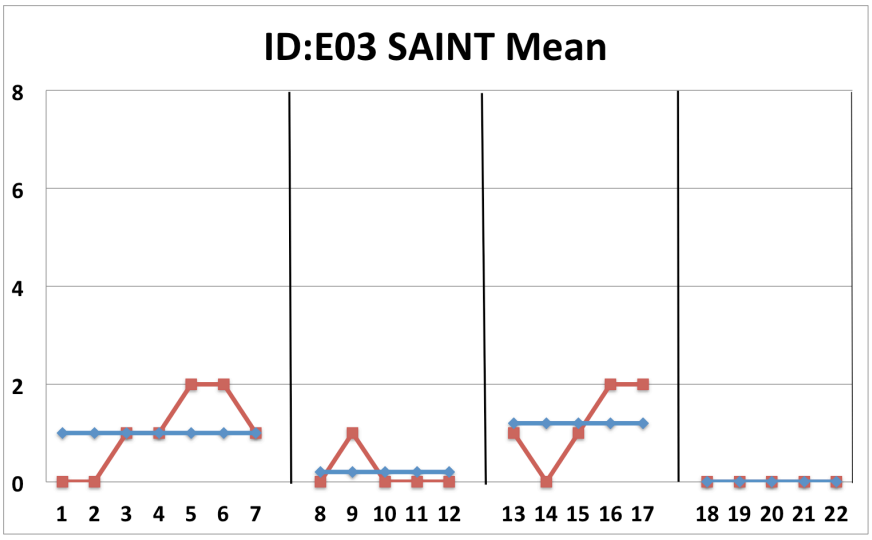
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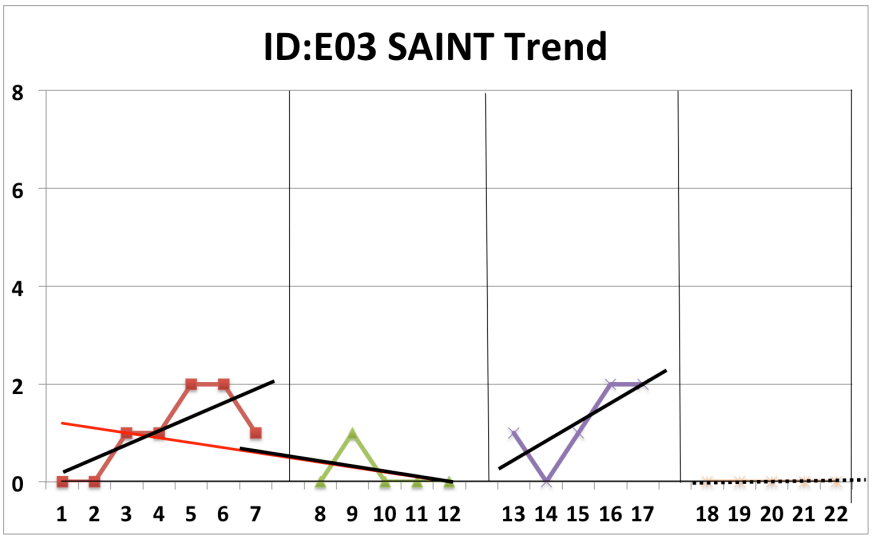
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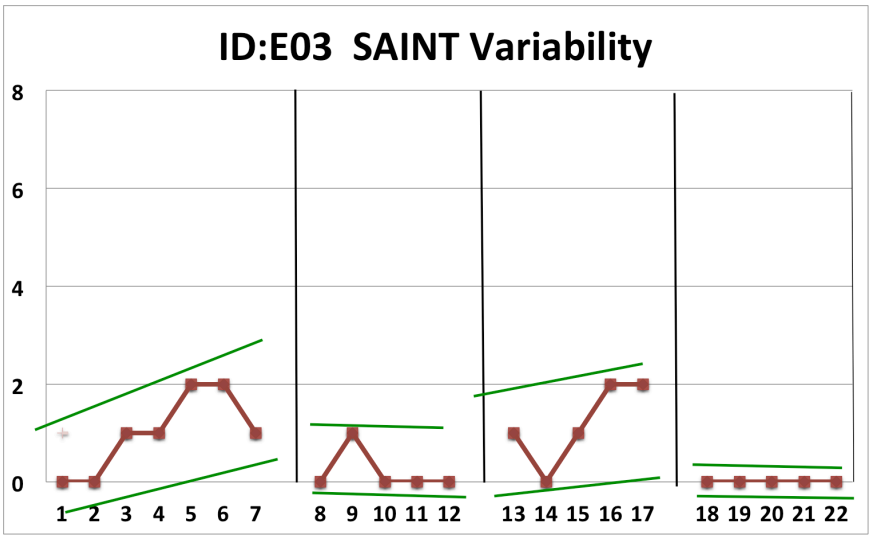
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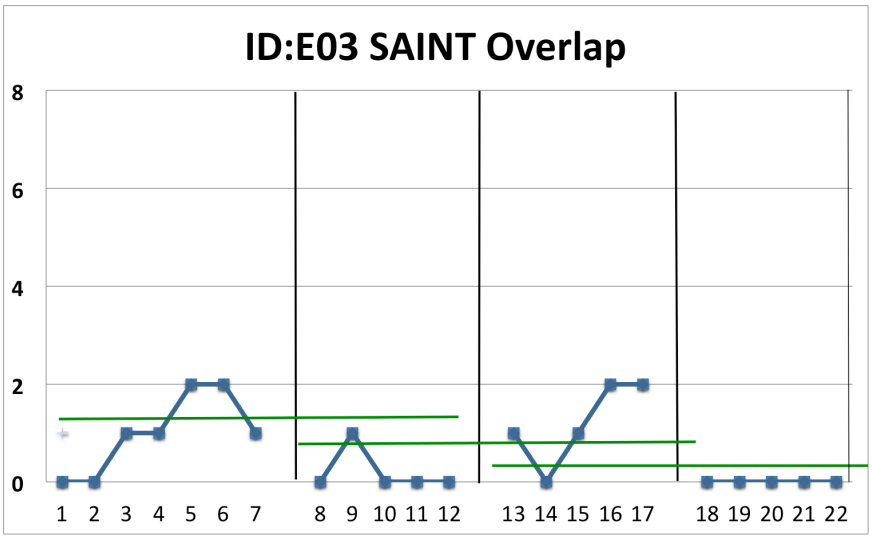
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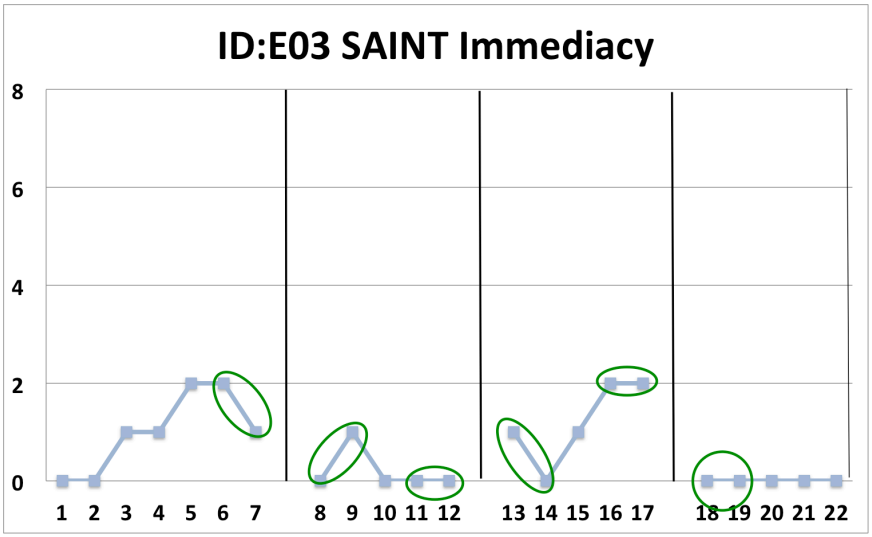
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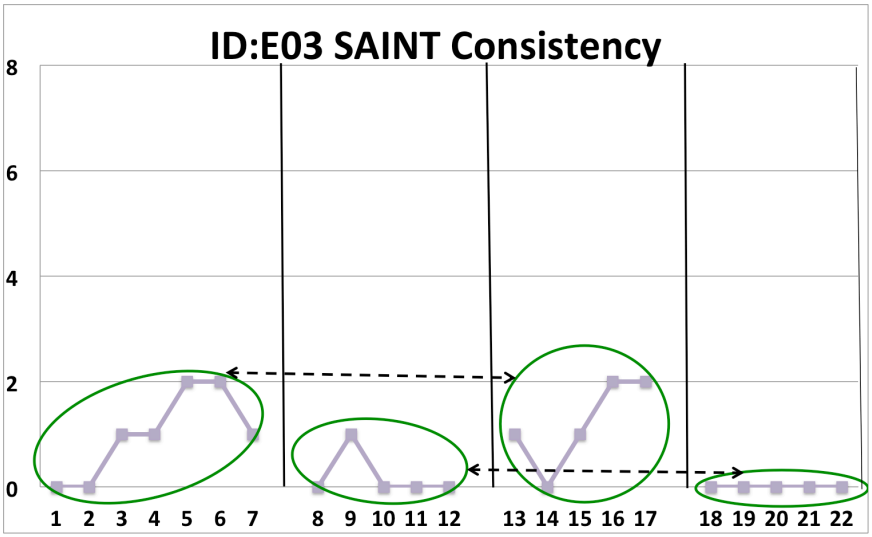
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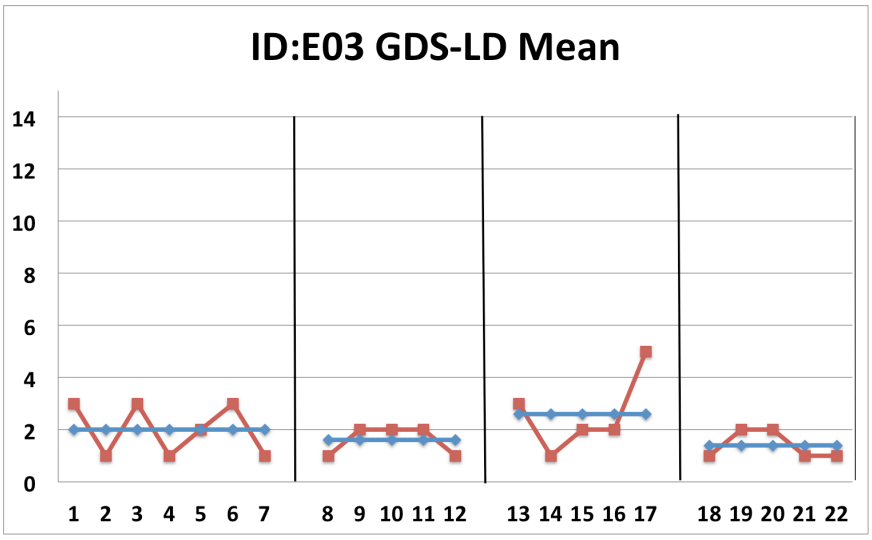
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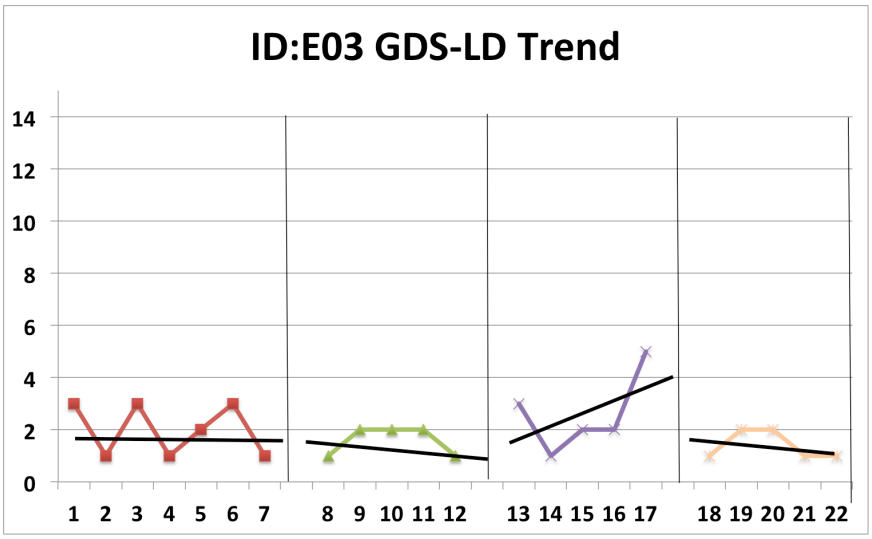
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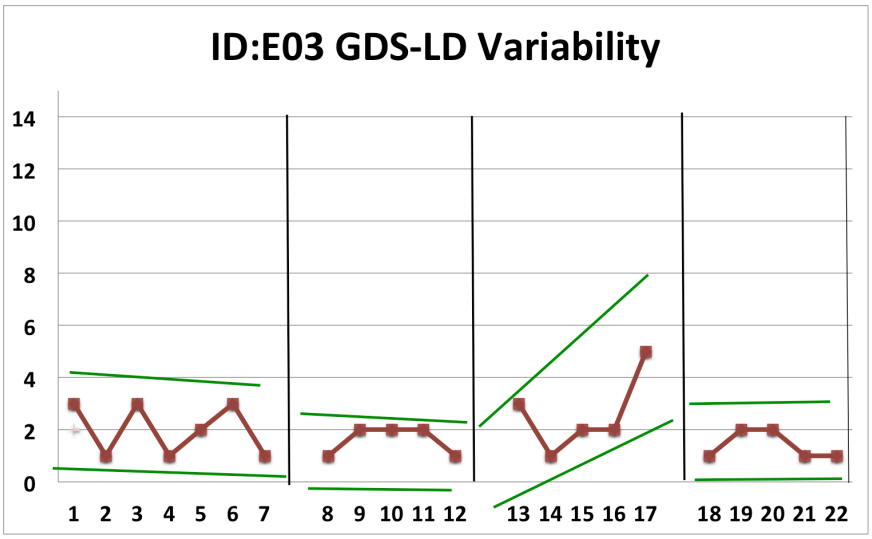
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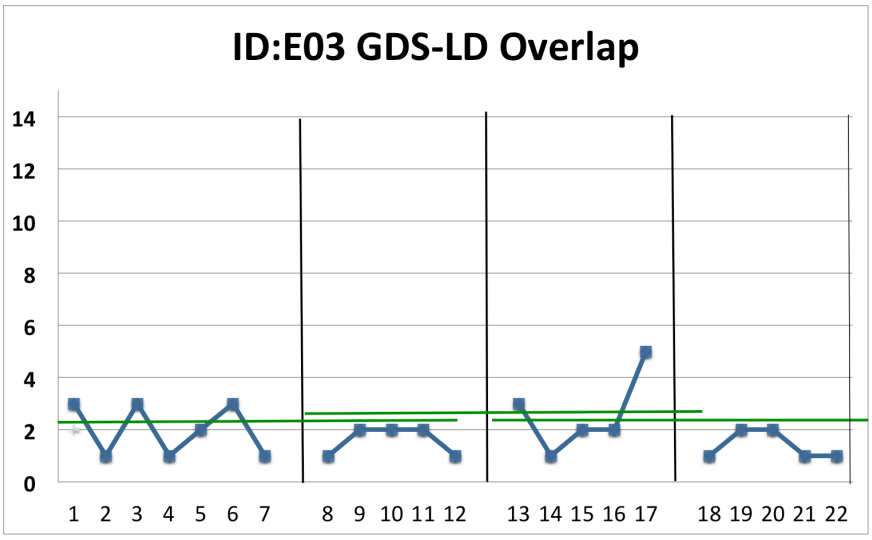
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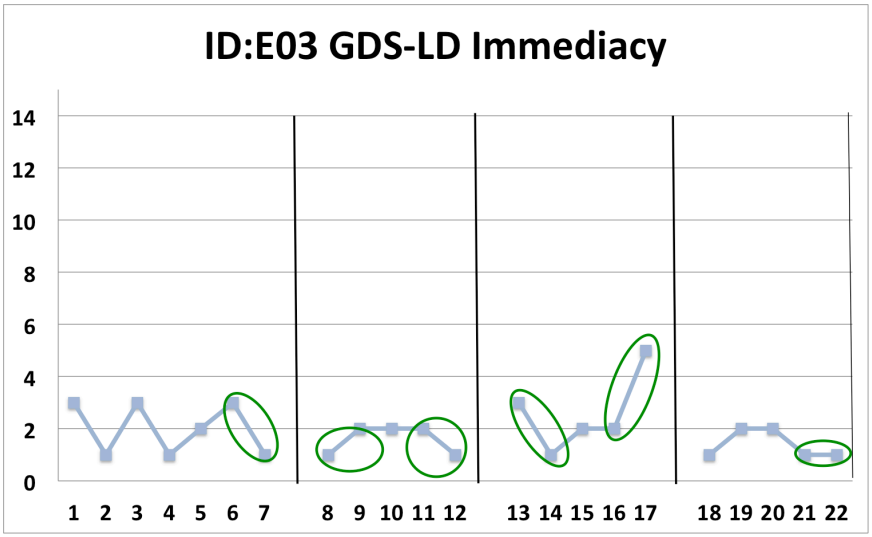
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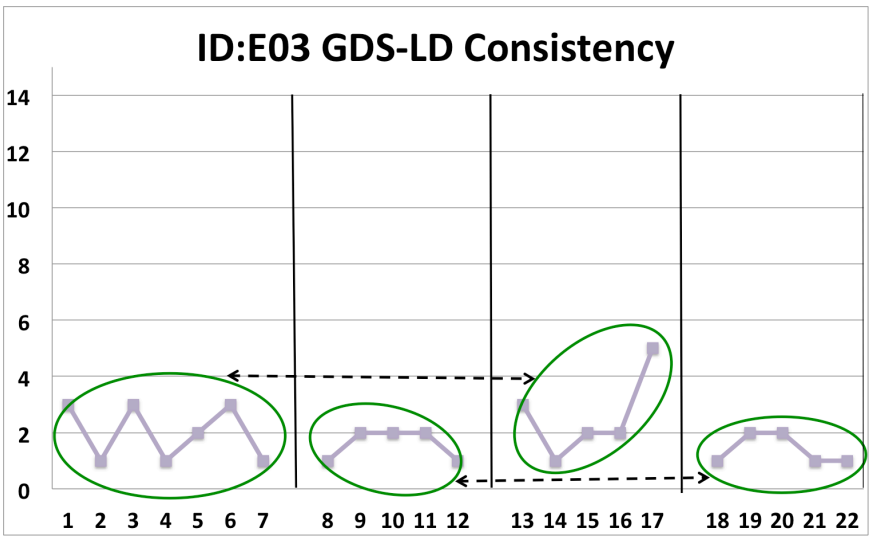
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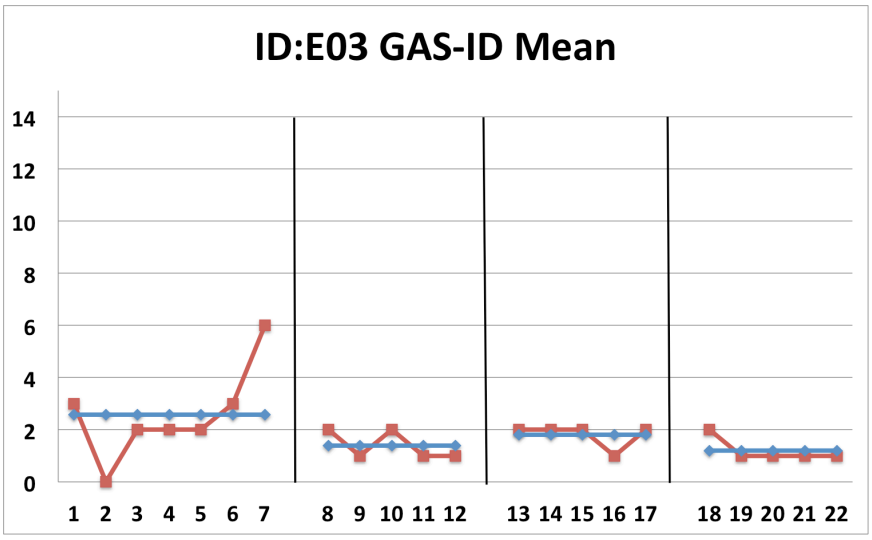
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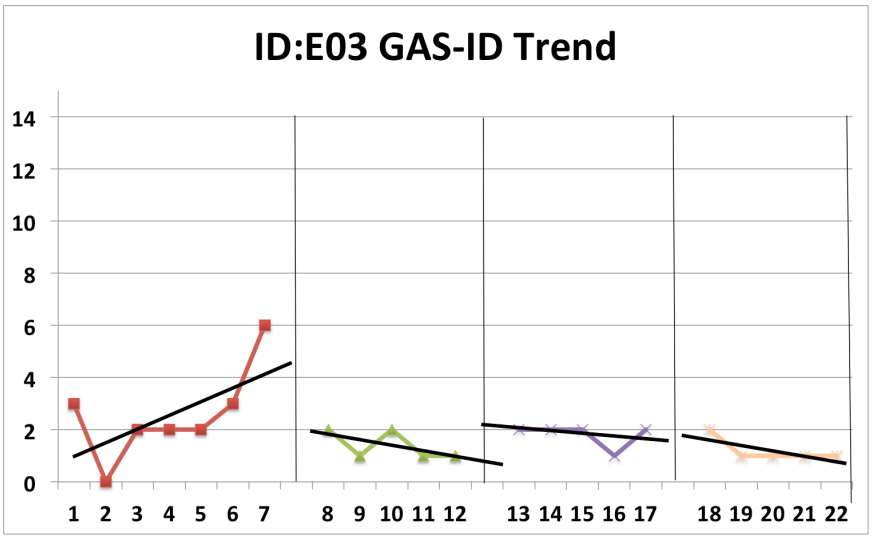
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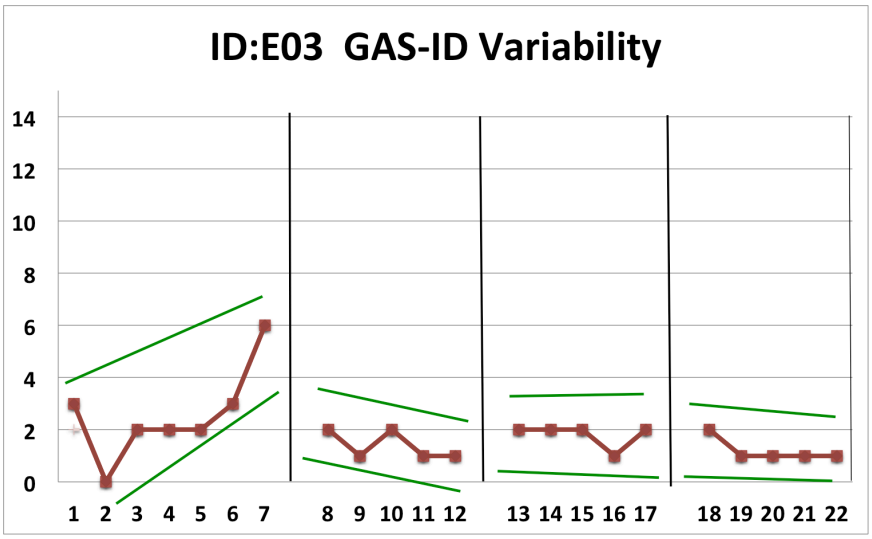
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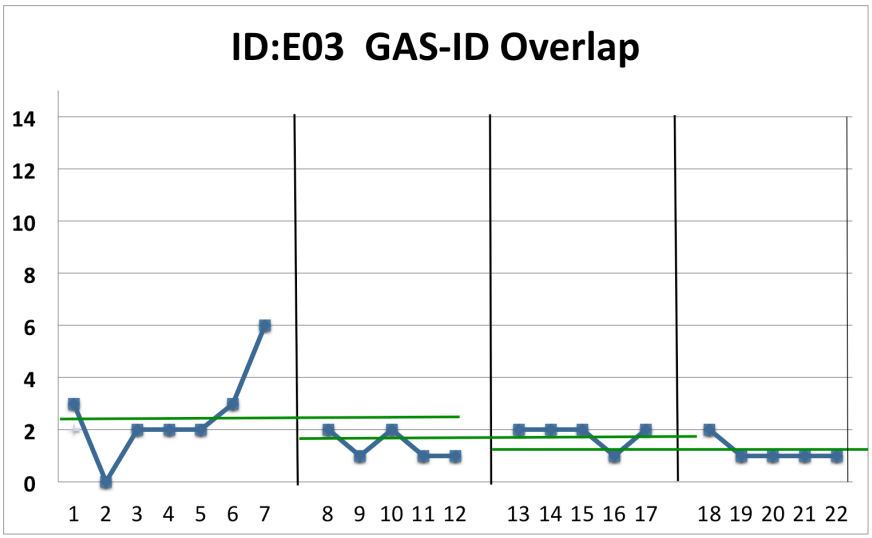
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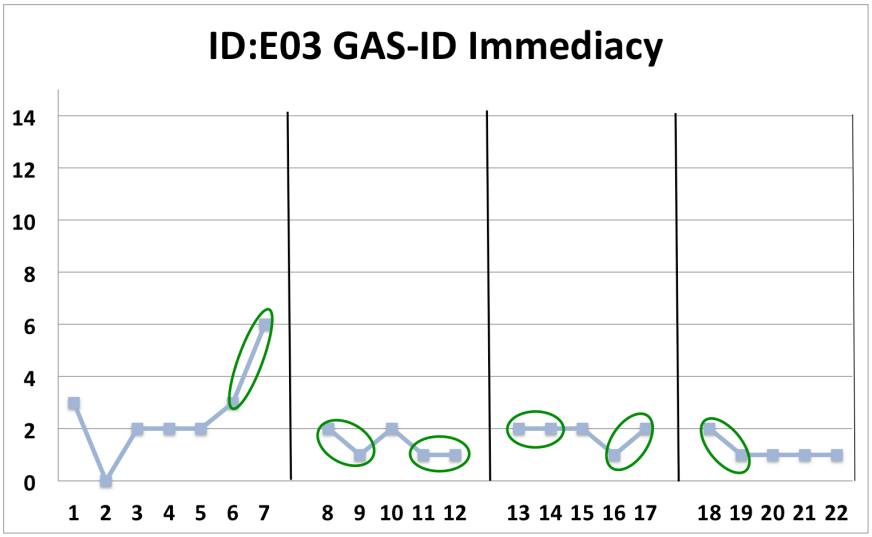
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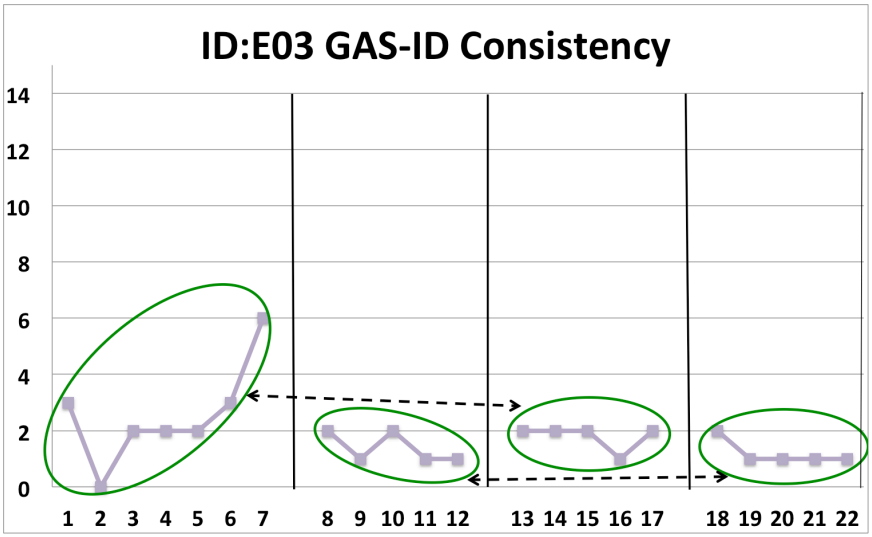
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RAW DATA FROM THE SERVICE USER AND CLINICAL EXPERT CONSULTATION

STUDY 1 Raw data and overview

This section provides the raw data for both the CE and SUE groups

STAGE 1 Results the user groups

Bexley 'beat the blues' round 1

The 'Beat the Blues" group met on 29th August 2008, and after having previously agreed to schedule this meeting as a research focus group. Ten people attended 7 of which consented to take part and have their opinions recorded anonymously. The 3 who did not consent remained with the group. Two did not participate in the discussions and 1 made comments that were highlighted and removed from the analysis.

1. How do people feel when they are becoming unwell? When do we know when we are at risk from becoming unwell?

The group generated a total of 20 responses listed below.

'I feel sick', 'I feel anxious', 'I feel pain', 'I feel mad', 'I feel strange', 'I feel angry', 'I feel tired', 'I feel afraid', 'I feel a bit rough', 'I feel stressed out', 'I feel scared', 'I am not sleeping', 'I have a temper'. 'I feel dizzy', 'I don't know who you are', 'I feel hot and cold', 'I have nightmares', 'I feel stress', 'I am not eating', 'I feel hate'.

In analysing the responses, certain patterns emerged i.e

1. Responses were expressed as a mixture of feelings and emotions such as sadness, anxiety

2. Responses were expressed as phenomena or events that had happened such as nightmares, responses to the immediate environment and/or situation such as I feel scared, I don't know who you are

3. Some responses were colloquial in that they are used generally when people are unable to articulate how they are feeling such as I feel a bit rough,. I feel hot and cold, I feel stressed out, I feel mad

Prior to the vote the answers I feel stress and I feel stressed out were merged with the agreement of the group. The group then voted on a top 10 from the remaining 19 choices.

FIG: Indicators recorded by the "Beat the Blues' group (29.08.2008)

Ranking	Best indicator	Votes and %
1=	I feel hot and cold	6 (8.6%)
1=	I feel stressed out (stress)	6 (8.6%)
1=	I feel tired	6 (8.6%)
4=	I feel dizzy	5 (7.1%)
4=	I am not sleeping	4 (5.7%)
4=	I am in pain	4 (5.7%)
7=	I have nightmares	4 (5.7%)
7=	I have a temper	4 (5.7%)
7=	I feel strange	4 (5.7%)
7=	I don't know who you are	4 (5.7%)
11=	I feel pain	3 (4.3%)
11=	I am not eating	3 (4.3%)
11=	I am scared	3 (4.3%)
11=	I am feeling a bit rough	3 (4.3%)
11=	I am feeling anxious	3 (4.3%)
11=	I am feeling scared	3 (4.3%)
17=	I am feeling sick	2 (2.9%)
17=	I am feeling angry	2 (2.9%)
19	I an feeling mad	1 (1.4%)

Key	Top 10

The second question

1. What activities, interventions or coping skills can help us to feel better about ourselves or help when we are feeling miserable or distressed?

Generated a total of 43 responses

Day trips, music, exercise, running, swimming, biking, walking, boxing, keep fit, hockey, football, shopping, puzzles, cuddle teddy, calm down, hobbies, stamps, art, deep breathing, keep busy, fresh air, relax, resting, soft music, reading a book, darts, dub reggae, bible, word searches, watch a DVD, snooker, cricket, tennis, socialising, talking to people, take pills, have a check up, phone Samaritans, phone Dr, call for X or Y (Community Nurses), talking to someone, puzzles.

These were cut down with the groups' agreement to 24. Talking to people was merged with socialising. This was defined as talking to people or a group for the purposes of this exercise, rather than confide in any one individual. This was because a number of the group expressed outside of the community learning disability team said there was no one they could trust to be able to talk to in private. Relax and resting was also merged. A number of sports were mentioned these were merged into one answer, sport with the sports listed individually as prompts. Other such as hobbies that encompassed more than one activity was listed individually as prompts within the main intervention. Music was listed as one category rather than any single genre e.g. dub reggae, reading the bible was expanded to include activities relating to all faiths. Puzzles were also used as a main category' and watching television was included with DVD.

The interventions were streamlined and categorised using a funnelling process and the following were agreed upon.

1. Sports i.e. cricket, football, boxing, tennis, biking, running
2. Hobbies i.e. art
3. Play games i.e. darts, bingo
4. Contact the team i.e. phone Doctor, Call for Ben and Heidi
5. Puzzles i.e. jigsaws, wordsearches
6. Listen to music

7. Read the … i.e. Bible, Quran, Torah
8. Reading a book
9. Watch a DVD
10. Talk to someone
11. Go for a trip out
12. Relax
13. Ring the Samaritans
14. Calm down
15. Deep breathing
16. Relax
17. Exercise i.e. walking
18. Resting
19. Keep Busy
20. Fresh air
21. Cuddle a teddy
22. Shopping
23. Check ups
24. Pills

Of these 24, 19 received one or more votes

FIG: Interventions recorded by the "Beat the Blues' group (29.08.2008)

Ranking	Intervention	Votes and %
1=	Have a check up	7 (8.4%)
1=	Day trips	7 (8.4%)
3=	Socialising	6 (7.2%)
3=	Take pills	6 (7.2%)
3=	Watch a DVD/TV	6 (7.2%)
3=	Puzzles	6 (7.2%)
3=	Keep busy	6 (7.2%)
8=	Relax /rest	5 (6%)
8=	Call for Ben or Heidi	5 (6%)
8=	Shopping	5 (6%)
8=	Music	5 (6%)
12=	Hobbies	4 (4.8%)
12=	Sport	4 (4.8%)
12=	Deep Breathing	4 (4.8%)
15=	Cuddle a teddy	2 (2.4%)
15=	Read a book	2 (2.4%)
17=	Reading a religious book	1 (1.2%)
17=	Fresh air	1 (1.2%)
17=	Phone Samaritans	1 (1.2%)

Key	Top 11

From the results, it was decided that relaxation would include strategies that promoted relaxation e.g. deep breathing, resting.

Lewisham "The Tuesday Group" round 1

The 'The Tuesday Group" group met on 29th September 2008, as a research focus group. Two people attended all of which consented to take part and have their opinions recorded anonymously. Both participants are experienced at presenting at conferences and training (with support) on user issues.

1. How do people feel when they are becoming unwell? When do we know when we are at risk from becoming unwell?

The group generated a total of 20 responses listed below.

'I feel run down, 'I feel physically unwell', 'I feel heartbroken', 'I feel mood swings', 'I feel uptight, 'I feel tense', 'I react badly to situations', 'I feel emotional', 'I feel I want to stop going out', 'I stop activities', 'I feel I loose interest in day to day life', 'I stay in bed', 'I loose concentration'. 'I feel worried', 'I feel anxious', 'I feel I have the shakes', 'I feel my heart pounding, 'I lose my appetite, 'I feel tingly,. "I feel upset".

In analysing the responses, certain patterns emerged i.e

1. Some responses would produce a sense of overwhelming and describe the consequences but not the symptoms that led to it e.g. I feel heartbroken

2. Other responses were expressed as how they were likely to react rather than the symptoms that made them feel like they did e.g. I feel I lose interest in day to day life e.g. I react badly to situations

Prior to the vote the answers mood swings, emotional and upset , were merged as were lose interest in day to day life, stop activities, stop going out; run down and physically unwell; worried and anxious with the agreement of the group. The group then voted on a top 10 from the remaining 14 choices.

FIG: Indicators recorded by the "The Tuesday Group" (14.09.2008)

Ranking	Best indicator	Votes and %
1=	I feel run down / physically unwell	2 (100%)
1=	I feel mood swings, / upset / emotional	2 (100%)
1=	I react badly to situations	2 (100%)
1=	I stay in bed	2 (100%)
1=	I feel heartbroken	2 (100%)
1=	I feel tense / uptight	2 (100%)
7=	I feel tingly	1 (50%)
7=	I have the shakes	1 (50%)
7=	I stop activities / stop going out / lose interest in day to day life	1 (50%)
7=	I lose my appetite	1 (50%)
7=	I feel worried / anxious	1 (50%)
7=	I lose my concentration	1 (50%)
13=	I feel my heart pounding	

Key	Top 13

The second question

2. What activities, interventions or coping skills can help us to feel better about ourselves or help when we are feeling miserable or distressed?

Generated a total of 15 responses

Talk to key worker, talk to family and friends, counselling, use a stress ball, breathing exercises, go out for a trip, Someone gives me time with them, Keep busy e.g. go to work, have a massage, go job hunting, go to classes, use the computer, do exercise, listen to soft music, have aromatherapy (scented candles), ring the Samaritans, go out to pubs, clubs and discos, socialise with people and go on holiday.

These were voted on without amendment and both participants agreed that all of the responses were good strategies to promote mental well being.

User groups round 2

This round took account of the results from the previous round and summarises the feedback for the consultation at the end of phase 2. The lists are drawn from the 40 responses in round 1. Where there is overlap responses have been merged.

Indicators that threaten mental well being.

1. I feel run down includes physically unwell, dizzy, pain,
2. I feel tense includes stressed out, stress, tense uptight
3. I lose my appetite
4. I feel anxious this includes feeling worried, I feel my heart pounding, I feel hot and cold, I feel tingly, I have the shakes
5. I feel emotional includes upset, mood swings, I feel heartbroken
6. I feel strange will include I don't know who you are
7. I am having problems with sleep nightmares, waking up, getting out of bed, I am not sleeping, I feel tired
8. I have a temper will include I react badly to situations
9. I lose my concentration
10. I find it difficult to do things merged from I have stopped activities, I am losing interest in day to day life, I have stopped going out

Interventions to promote good mental health

From the 58 answers we got from the two groups the interventions that were most popular were funnelled into the following list.

1. Speak to someone in your team includes having a check up, take pills, talk to key worker, see a counsellor have a check up, call for Ben or Heidi
2. Speak to some one outside your team you trust. This includes the Samaritans, talk to family and friends, some one who can give you time
3. Socialise includes day trips, pub, disco and clubs

4. Watch TV or DVD
5. Listen to music includes soft music
6. Keep busy. This includes job hunting, go to classes, use the computer, go shopping
7. Do exercises. This includes sports and activities such as walking
8. Relax and rest. This includes using a stress ball, breathing exercises, aromatherapy or scented candles, get some fresh air
9. Do hobbies. This includes stamp collecting, puzzles
10. Other reading, comforter such as cuddle a teddy, play games

4.4.4 Delphi User Groups round 2

Round 2 involved the self report phrases and coping strategies being listed along with a separate list generated by the expert consensus in round 1. These were formatted using two designs to improve clarity and accessibility.

1. A3 sheet with similar items colour coded between the user and expert groups
2. A4 large font lists for side by side comparison

Lists with no modifications were also available.

Round 2 'The Tuesday Group' round 2 21.10.2008

Initially the results from both the service user consultations in round 1 were fed back. For this round there were 3 participants. The group confirmed that they wanted all of the self-report statements to be kept. They were then asked to choose which they felt were the most helpful and least helpful statements. No statements were though t to be negative whilst 'losing appetite', 'feeling anxious', 'problems sleeping' were thought to be the most helpful. Nest the results of the expert group were fed back. It was fed back that a number were similar and in round 3 both the self-report statements and coping strategies would have examples e.g.

1. 'I have trouble sleeping' or 'sleeping is causing me problems'
    a. I am having nightmares
    b. I keep waking in the night
    c. I wake up very early
    d. I find it difficult to get to sleep

e. I keep falling asleep during the day

Round 2 Woolwich 'Beat the Blues' 24.10.2008

The group numbered 8 and agreed to retain all of the self-report statements from round 1 and were then asked which they felt were the best of the statements. Those with additional votes were ranked as follows

'Sleeping' 37.5% (3), 'tense' 25% (2), ''emotional', 'concentration', lose interest', lose appetite, all 12.5% (1).

From the expert answers the group did not endorse those self reports expressed as outcomes such as being violent or self harm, But agreed their inclusion if made clear they that described feelings rather than an act. Strange thoughts, and hearing voices was included, with the group having experienced a range of symptoms when mentally unwell.

4.4.7 The coping strategies

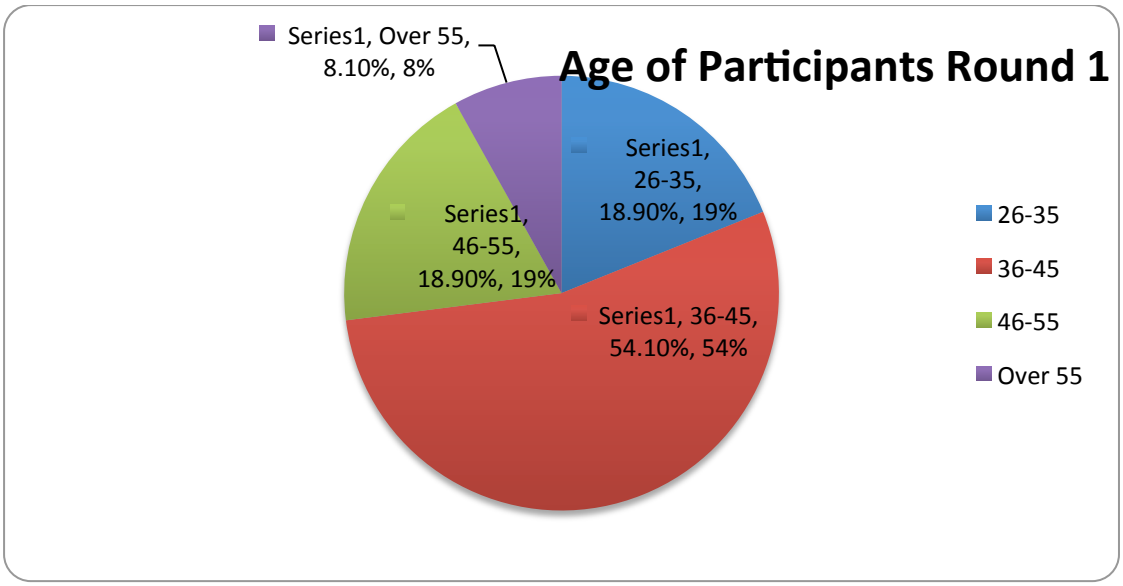
The same process was followed and 'socialising' 25% (2) listen to music 12.5% (1). Ideas from the expert group got a mixed response reading a book was not as popular with 25% (2) expressing dissent as was looking at a photo album 25% (2), many felt that photos even ones they treasured made them sad. What was popular was 'getting away from problems' and 'not answering back', both 50% (4). This was I direct contrast to the other user group

Delphi Clinical expert group

Results round 1 27.08.2008 - 13.10.2008

Response summary: In all 98 emails were sent to experts. Of these 19 bounced or were not received. Therefore 79 emails were received. A link was also sent with the email and notice of the study was placed on two national networks. In all 38 people completed the Delphi. A reminder email was sent in week 4

Total questionnaires completed 38 (100%). In terms of demographic profile of the respondents 55.3% (21) were female, 83.8% (31) recorded themselves as white or white British, 8.1% (3). Black or Black British and 5,4 mixed race or other. The majority of respondents were Nurses 53.1% (17) followed by Psychiatrists 25% (8).



In terms of occupation 53% (17) of respondents were nurses and 25% (8) Psychiatrists, the rest were made up form a range of professions including, Psychologist, Occupational Therapists, Behaviour Support Nurses as well as lecturer and academic posts.

The self report statements were for the majority positive. The table below gives a rating average for all items considered.

FIG:

5. Please rate the following self report statements as to whether they are likely to help a person with intellectual disabilities predict that their emotional or mental well being might beat risk.

	Strongly agree risk to mental health	Agree	Neither agree or disagree	Disagree	Strongly disagree to mental health	Rating Average	Response Count
1. I have little interest or pleasure in doing things.	18.4% (7)	**50.0% (19)**	13.2% (5)	18.4% (7)	0.0% (0)	3.68	38
2. I am feeling sad.	21.1% (8)	**63.2% (24)**	7.9% (3)	7.9% (3)	0.0% (0)	3.97	38
3. I have trouble with sleeping.	21.1% (8)	**52.6% (20)**	18.4% (7)	7.9% (3)	0.0% (0)	3.87	38
4. I am feeling tired or have little energy.	15.8% (6)	**55.3% (21)**	18.4% (7)	10.5% (4)	0.0% (0)	3.76	38
5. I am overeating.	7.9% (3)	34.2% (13)	**42.1% (16)**	15.8% (6)	0.0% (0)	3.34	38
6. I feel I have let myself or other people down.	13.2% (5)	**50.0% (19)**	13.2% (5)	23.7% (9)	0.0% (0)	3.53	38
7. I am feeling bad about myself	31.6% (12)	**47.4% (18)**	7.9% (3)	13.2% (5)	0.0% (0)	3.97	38
8. I have trouble concentrating	5.3% (2)	**52.6% (20)**	28.9% (11)	13.2% (5)	0.0% (0)	3.50	38
9. I feel I am moving so slowly that other people could have	13.2% (5)	26.3% (10)	**39.5% (15)**	13.2% (5)	7.9% (3)	3.24	38

	Strongly agree risk to mental health	Agree	Neither agree or disagree	Disagree	Strongly disagree to mental health	Rating Average	Response Count
noticed							
10. I feel restless	2.6% (1)	**50.0% (19)**	31.6% (12)	15.8% (6)	0.0% (0)	3.39	38
11. I have thoughts that I would be better off dead or of hurting myself in some way	**60.5% (23)**	23.7% (9)	5.3% (2)	2.6% (1)	7.9% (3)	4.26	38
12. I am hearing things that are not there	**44.7% (17)**	36.8% (14)	7.9% (3)	0.0% (0)	10.5% (4)	4.05	38
13. I don't feel like eating	18.4% (7)	**47.4% (18)**	23.7% (9)	5.3% (2)	5.3% (2)	3.68	38
14. I am having problems with sleeping	18.4% (7)	**60.5% (23)**	13.2% (5)	7.9% (3)	0.0% (0)	3.89	38
15. I think people know what I am thinking	**36.8% (14)**	34.2% (13)	13.2% (5)	10.5% (4)	5.3% (2)	3.87	38
16. I believe people can play with my thoughts	**47.4% (18)**	18.4% (7)	15.8% (6)	10.5% (4)	7.9% (3)	3.87	38
17. I feel that people don't like me	7.9% (3)	**42.1% (16)**	**42.1% (16)**	2.6% (1)	5.3% (2)	3.45	38
18. I feel like I am in a panic	13.2% (5)	**60.5% (23)**	18.4% (7)	2.6% (1)	5.3% (2)	3.74	38

	Strongly agree risk to mental health	Agree	Neither agree or disagree	Disagree	Strongly disagree to mental health	Rating Average	Response Count
19. I feel very grand	18.4% (7)	18.4% (7)	**34.2% (13)**	23.7% (9)	5.3% (2)	3.21	38
20. I feel very excited	5.3% (2)	31.6% (12)	**39.5% (15)**	15.8% (6)	7.9% (3)	3.11	38
21. I feel like I can do anything	10.5% (4)	**39.5% (15)**	31.6% (12)	13.2% (5)	5.3% (2)	3.37	38
22. I feel parts of my body are not there	28.9% (11)	**44.7% (17)**	10.5% (4)	10.5% (4)	5.3% (2)	3.82	38
23. I feel like I have a lot of problems	15.8% (6)	**44.7% (17)**	26.3% (10)	10.5% (4)	2.6% (1)	3.61	38
24. I can't do the things people want me to do	2.6% (1)	36.8% (14)	**39.5% (15)**	18.4% (7)	2.6% (1)	3.18	38
25. I feel anxious	5.3% (2)	**71.1% (27)**	15.8% (6)	5.3% (2)	2.6% (1)	3.71	38
26. I feel people can control me	18.4% (7)	**42.1% (16)**	21.1% (8)	13.2% (5)	5.3% (2)	3.55	38
27. I feel I cant go on	36.8% (14)	**44.7% (17)**	7.9% (3)	5.3% (2)	5.3% (2)	4.03	38
28. I feel people hate me	13.2% (5)	**55.3% (21)**	13.2% (5)	13.2% (5)	5.3% (2)	3.58	38
29. I feel people don't listen to me	2.6% (1)	**42.1% (16)**	31.6% (12)	18.4% (7)	5.3% (2)	3.18	38
30. I am worried about taking my	10.5% (4)	21.1% (8)	**47.4% (18)**	18.4% (7)	2.6% (1)	3.18	38

	Strongly agree risk to mental health	Agree	Neither agree or disagree	Disagree	Strongly disagree to mental health	Rating Average	Response Count
medication							
31. I am having trouble rememberin g things	5.3% (2)	36.8% (14)	**42.1% (16)**	15.8% (6)	0.0% (0)	3.32	38
32. I feel I cannot talk to others	7.9% (3)	**44.7% (17)**	28.9% (11)	18.4% (7)	0.0% (0)	3.42	38
33. I feel people cannot understand me	2.6% (1)	**36.8% (14)**	**36.8% (14)**	21.1% (8)	2.6% (1)	3.16	38
34. I feel I cannot concentrate	0.0% (0)	**42.1% (16)**	36.8% (14)	13.2% (5)	7.9% (3)	3.13	38
35. I have had a seizure/fit today	10.5% (4)	15.8% (6)	**34.2% (13)**	18.4% (7)	21.1% (8)	2.76	38
36. I feel am not looking after myself	2.6% (1)	**52.6% (20)**	31.6% (12)	10.5% (4)	2.6% (1)	3.42	38
37. I am having problems getting on with people	0.0% (0)	28.9% (11)	**50.0% (19)**	18.4% (7)	2.6% (1)	3.05	38
38. I feel angry	7.9% (3)	**44.7% (17)**	26.3% (10)	15.8% (6)	5.3% (2)	3.34	38
39. I feel like hurting myself	39.5% (15)	**47.4% (18)**	2.6% (1)	2.6% (1)	7.9% (3)	4.08	38
40. I feel like hitting someone	15.8% (6)	**44.7% (17)**	23.7% (9)	7.9% (3)	7.9% (3)	3.53	38
41. I feel like breaking things	15.8% (6)	**47.4% (18)**	23.7% (9)	7.9% (3)	5.3% (2)	3.61	38

	Strongly agree risk to mental health	Agree	Neither agree or disagree	Disagree	Strongly disagree to mental health	Rating Average	Response Count
42. I feel like doing something that will get me into trouble	13.2% (5)	**47.4% (18)**	23.7% (9)	10.5% (4)	5.3% (2)	3.53	38
43. I feel like cutting myself	**50.0% (19)**	28.9% (11)	10.5% (4)	2.6% (1)	7.9% (3)	4.11	38
44. I want to die	**55.3% (21)**	34.2% (13)	0.0% (0)	2.6% (1)	7.9% (3)	4.26	38
45. I have been drinking and/or taking drugs	10.5% (4)	**52.6% (20)**	15.8% (6)	18.4% (7)	2.6% (1)	3.50	38
46. I feel I am dangerous	28.9% (11)	**42.1% (16)**	15.8% (6)	5.3% (2)	7.9% (3)	3.79	38
47. I feel I am going to get someone	18.4% (7)	**47.4% (18)**	18.4% (7)	7.9% (3)	7.9% (3)	3.61	38
48. I feel like threatening someone	15.8% (6)	**50.0% (19)**	13.2% (5)	13.2% (5)	7.9% (3)	3.53	38
49. I don't want to be alive	**52.6% (20)**	36.8% (14)	0.0% (0)	2.6% (1)	7.9% (3)	4.24	38
50. I feel out of control	18.4% (7)	**52.6% (20)**	13.2% (5)	10.5% (4)	5.3% (2)	3.68	38
51. I feel people stop me from doing what I want	5.3% (2)	26.3% (10)	**39.5% (15)**	18.4% (7)	10.5% (4)	2.97	38
52. I cannot stand the noise and/or fuss	5.3% (2)	**42.1% (16)**	34.2% (13)	13.2% (5)	5.3% (2)	3.29	38

	Strongly agree risk to mental health	Agree	Neither agree or disagree	Disagree	Strongly disagree to mental health	Rating Average	Response Count
answered question							
38							

There were a number of additional comments which were recorded and incorporated in the 2nd round of the Delphi which are listed below. There was some overlap between some of the self report statements. Where this occurred statements were merged for the second round.

Please write below any comments that you feel should be added to the feelings list above.

1. I feel there are things crawling on/under my skin

2. Nothing to add.

3. Feelings of hyper-sexuality/increased sexual arousal .e.g. I feel more sexy than usual. Increased desire to "self medicate" via substance misuse.eg I am getting drunk more than usual or I drink to cheer myself up. Self neglect e.g. I have stopped bathing and changing my clothes.

4. I feel that my life will never get any better I feel that nobody cares about me

5. i found it difficult to rate some of these emotions without contextual factors being known such as the statement about medication it maybe that there is legitimate worries through lack of information and explanation that would only be at risk of affecting physical and emotional well being if those worries influenced a decision to stop taking medication with out medical advice.

7. There were no symptoms regarding emotional states (i.e. crying, etc), somatic symptoms (i.e. headache, stomach problems, etc) also atypical symptoms (i.e. aggression, challenging behaviours, screaming)

9. I think some people require further information to help them understand their feelings. For example, having examples to illustrate the statement or using visual images can aid understanding. Asking people to take photos of their everyday life so they can be used during an assessment can also expand a dialogue between the clinician and person/patient.

10. It is not clear whether you are targeting mental health problems in general, or depression - the tool should be more focused. I have therefore rated all items not

directly relevant to depression as neither agree or disagree. Furthermore, many of the items are worded in a complex or ambivalent way, and would not be easily understood.

In rating potential coping strategies and interventions which could promote mental well being, again there were non negative responses for any of the items. 20% (4) neither agreed nor disagreed whilst 80% (16) either strongly agreed or agreed.

***FIG:* 7. Please rate the following coping strategies on how effective they are in helping someone with intellectual disabilities whose mental health is vulnerable.**

	Strongly agree promotes mental well being	Agree	Neither agree or disagree	Disagree	Strongly disagree activity promotes mental well being	Rating Average	Response Count
1. Going to the gym	10.5% (4)	**71.1% (27)**	15.8% (6)	2.6% (1)	0.0% (0)	3.89	38
2. Read a book	5.3% (2)	21.1% (8)	**50.0% (19)**	21.1% (8)	2.6% (1)	3.05	38
3. Doing exercise	31.6% (12)	**65.8% (25)**	2.6% (1)	0.0% (0)	0.0% (0)	4.29	38
4. Listen to music	18.4% (7)	**76.3% (29)**	5.3% (2)	0.0% (0)	0.0% (0)	4.13	38
5. Tidy my room.	5.3% (2)	34.2% (13)	**47.4% (18)**	13.2% (5)	0.0% (0)	3.32	38
6. Go for a walk	21.1% (8)	**78.9% (30)**	0.0% (0)	0.0% (0)	0.0% (0)	4.21	38
7. Ring someone I know to talk to	**50.0% (19)**	42.1% (16)	7.9% (3)	0.0% (0)	0.0% (0)	4.42	38
8. Talk to someone close to me	**57.9% (22)**	39.5% (15)	2.6% (1)	0.0% (0)	0.0% (0)	4.55	38
9. Write about what	18.4% (7)	**57.9% (22)**	21.1% (8)	2.6% (1)	0.0% (0)	3.92	38

	Strongly agree promotes mental well being	Agree	Neither agree or disagree	Disagree	Strongly disagree activity promotes mental well being	Rating Average	Response Count
upsets me							
10. Visit a friend or family	26.3% (10)	**63.2% (24)**	10.5% (4)	0.0% (0)	0.0% (0)	4.16	38
11. Go to the library	0.0% (0)	31.6% (12)	**52.6% (20)**	15.8% (6)	0.0% (0)	3.16	38
12. Do relaxation exercises	31.6% (12)	**65.8% (25)**	2.6% (1)	0.0% (0)	0.0% (0)	4.29	38
13. Take deep breathes	34.2% (13)	**57.9% (22)**	5.3% (2)	2.6% (1)	0.0% (0)	4.24	38
14. Tell myself I will be OK	18.4% (7)	**60.5% (23)**	15.8% (6)	5.3% (2)	0.0% (0)	3.92	38
15. Tell and remind myself how well I coped before in similar situations	44.7% (17)	**55.3% (21)**	0.0% (0)	0.0% (0)	0.0% (0)	4.45	38
16. Get away from what is upsetting me	31.6% (12)	**47.4% (18)**	21.1% (8)	0.0% (0)	0.0% (0)	4.11	38
17. Try not to make things worse by arguing	15.8% (6)	**44.7% (17)**	34.2% (13)	5.3% (2)	0.0% (0)	3.71	38
18. Ring someone for help on a	26.3% (10)	**63.2% (24)**	7.9% (3)	2.6% (1)	0.0% (0)	4.13	38

	Strongly agree promotes mental well being	Agree	Neither agree or disagree	Disagree	Strongly disagree activity promotes mental well being	Rating Average	Response Count
helpline e.g Samaritans							
19. Go to my room	2.6% (1)	39.5% (15)	**50.0% (19)**	7.9% (3)	0.0% (0)	3.37	38
20. Write in my diary how I will cope	10.5% (4)	**68.4% (26)**	18.4% (7)	2.6% (1)	0.0% (0)	3.87	38
answered question							**38**
skipped question							**0**

Again there were comments on the process and additional coping strategies suggested. These were incorporated into the second round.

FIG: **8. Please write below any strategies or coping strategies that you feel should be added to the list above**

1. Draw a picture about how I am feeling Think about something happy
2. Nothing to add
3. again these will be influenced by contextual factors and a persons preferences and cognitive abilities
4. Watching a favourite DVD Looking at a photo album Arranging to go out with a friend Inviting a friend for dinner
5. N/A
6. There is no mention of medication, psychological therapies, employment, education, recreation activities, friendships / relationships / marriage / children, achieving aspirations, use of alcohol, diet, information leaflets, support groups, living independent / with others

7. Very difficult to answer as some are good s-t strategies, such as getting away from what is upsetting, but are not useful in the long-term, as avoidance is not helpful. Playing a tape with the voice of someone to whom I'm close Looking at pictures that remind me of happy times and/or ways of coping Carrying out an activity I enjoy, such as gardening or taking something to be mended, however limited

8. regular or PRN medications

9. see

10. For some of the statements it depends if the person has sufficient literacy skills to read a book or ring a friend.

11. dependent upon severity of LD, focus upon reading etc may be inappropriate but could use doing things that you like doing

Both the self report statements and the coping strategies were ranked in order using a rating average. These were then along with the service user results were given to participants to inform the second round. Following merging of similar categories.

Self report statements

		Rating Average
1	I have thoughts that I would be better off dead or of hurting myself in some way	4.26
1	I want to die	4.26
2	I don't want to be alive	4.24
3	I feel like cutting myself	4.11
4	I feel like hurting myself	4.08
5	I am hearing things that are not there	4.05
6	I feel I cant go on	4.03
7	I am feeling sad.	3.97
7	I am feeling bad about myself	3.97
9	I am having problems with sleeping	3.89
10	I have trouble with sleeping.	3.87
10	I think people know what I am thinking	3.87
10	I believe people can play with my thoughts	3.87

13	I feel parts of my body are not there	3.82
14	I feel I am dangerous	3.79
15	I am feeling tired or have little energy.	3.76
16	I feel like I am in a panic	3.74
17	I feel anxious	3.71
18	I have little interest or pleasure in doing things.	3.68
18	I don't feel like eating	3.68
18	I feel out of control	3.68
21	I feel like I have a lot of problems	3.61
21	I feel like breaking things	3.61
21	I feel I am going to get someone	3.61
24	I feel people hate me	3.58
25	I feel people can control me	3.55
26	I feel I have let myself or other people down.	3.53
26	I feel like hitting someone	3.53
26	I feel like doing something that will get me into trouble	3.53
26	I feel like threatening someone	3.53
30	I have trouble concentrating	3.5
30	I have been drinking and/or taking drugs	3.5

FIG: COPING STRATEGIES

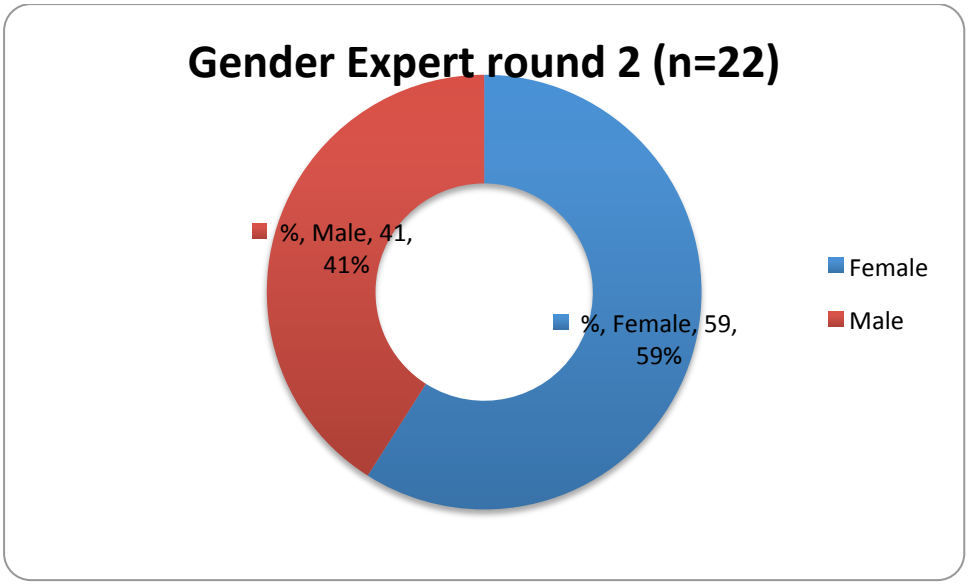
		Rating Average
1	Talk to someone close to me	4.55
2	Tell and remind myself how well I coped before in similar situations	4.45
3	Ring someone I know to talk to	4.42
4	Doing exercise	4.29

4	Do relaxation exercises	4.29
6	Take deep breathes	4.24
7	Go for a walk	4.21
8	Visit a friend or family	4.16
9	Listen to music	4.13
9	Ring someone for help on a helpline e.g Samaritans	4.13
11	Get away from what is upsetting me	4.11
12	Write about what upsets me	3.92
12	Tell myself I will be OK	3.92
14	Going to the gym	3.89
15	Write in my diary how I will cope	3.87
16	Try not to make things worse by arguing	3.71
17	Go to my room	3.37
18	Tidy my room.	3.32
19	Go to the library	3.16
20	Read a book	3.05

Clinical Experts results round 2 sent 12.10.2008

Response summary: The second round was by invite only. A total of 33 emails containing the questionnaire for round 2 were sent to experts. In all 22 people completed the Delphi. A reminder email was sent in week 3

Total questionnaires completed 22 (66%)



2. What is your ethnic background?

	Response Percent	**Response Count**
White / White British	**86.4%**	19
Black / Black British	4.5%	1
Mixed Background	4.5%	1
Other Ethnic Group	4.5%	1

FIG: 3. What is your age?

	Response Percent	**Response Count**
26-35	9.1%	2
36-45	**54.5%**	12
46-55	31.8%	7
Over 55	4.5%	1

4. What do you consider to be your main occupation (n=19)

	Response Percent	Response Count
Psychiatrist	42.1%	8
Lecturer	5.3%	1
Researcher	5.3%	1
Psychologist	5.3%	1
Nurse	**47.4%**	9

FIG: Self Report statements

	Strongly agree indicates a risk to mental health	Agree	Neither agree or disagree	Disagree	Strongly disagree indicates a risk to mental health	Rating Average	Response Count
I have thoughts that I would be better off dead includes I want to die I don't want to be alive	**68.2% (15)**	27.3% (6)	4.5% (1)	0.0% (0)	0.0% (0)	4.64	22
I feel like cutting myself Includes I feel like hurting myself hurting myself in some way	**54.5% (12)**	40.9% (9)	4.5% (1)	0.0% (0)	0.0% (0)	4.50	22
I feel emotional includes upset, mood swings,	9.1% (2)	**86.4% (19)**	4.5% (1)	0.0% (0)	0.0% (0)	4.05	22

I feel heartbroken							
I feel run down includes physically unwell, dizzy, pain,	4.5% (1)	**59.1% (13)**	31.8% (7)	4.5% (1)	0.0% (0)	3.64	22
I feel tense includes stressed out, stress, tense uptight	18.2% (4)	**72.7% (16)**	9.1% (2)	0.0% (0)	0.0% (0)	4.09	22
I am hearing things that are not there	**63.6% (14)**	36.4% (8)	0.0% (0)	0.0% (0)	0.0% (0)	4.64	22
I feel strange	4.5% (1)	**45.5% (10)**	**45.5% (10)**	4.5% (1)	0.0% (0)	3.50	22
I don't know who you are	13.6% (3)	18.2% (4)	**50.0% (11)**	13.6% (3)	4.5% (1)	3.23	22
I feel I cant go on	**45.5% (10)**	**45.5% (10)**	9.1% (2)	0.0% (0)	0.0% (0)	4.36	22
I am feeling sad.	4.5% (1)	**59.1% (13)**	36.4% (8)	0.0% (0)	0.0% (0)	3.68	22
I am feeling bad about myself	4.5% (1)	**68.2% (15)**	22.7% (5)	4.5% (1)	0.0% (0)	3.73	22
I am having problems with sleeping includes I have trouble with sleeping. I am having problems with sleep nightmares, waking up, getting out of bed, I am not sleeping, I feel tired	31.8% (7)	**59.1% (13)**	9.1% (2)	0.0% (0)	0.0% (0)	4.23	22
I think people know what I am thinking	**59.1% (13)**	31.8% (7)	4.5% (1)	4.5% (1)	0.0% (0)	4.45	22

includes I believe people can play with my thoughts I feel people can control me							
I feel there are things crawling on/under my skin	**40.9% (9)**	36.4% (8)	18.2% (4)	4.5% (1)	0.0% (0)	4.14	22
I feel parts of my body are not there	**40.9% (9)**	31.8% (7)	22.7% (5)	4.5% (1)	0.0% (0)	4.09	22
I feel out of control includes I feel I am dangerous I feel I am going to get someone I feel like threatening someone I have a temper will include I react badly to situations	27.3% (6)	**54.5% (12)**	13.6% (3)	4.5% (1)	0.0% (0)	4.05	22
I am feeling tired or have little energy.	0.0% (0)	**68.2% (15)**	27.3% (6)	4.5% (1)	0.0% (0)	3.64	22
I feel like I am in a panic includes I feel anxious I feel anxious this includes feeling worried, I feel my heart pounding, I feel hot and cold, I feel tingly, I have the shakes	40.9% (9)	**50.0% (11)**	4.5% (1)	4.5% (1)	0.0% (0)	4.27	22
I find it	27.3% (6)	**72.7%**	0.0% (0)	0.0% (0)	0.0% (0)	4.27	22

difficult to do things includes I have stopped activities, I am losing interest in day to day life, I have stopped going out		**(16)**					
I don't feel like eating I lose my appetite	22.7% (5)	**59.1% (13)**	18.2% (4)	0.0% (0)	0.0% (0)	4.05	22
I have stopped bathing and changing my clothes.	36.4% (8)	**54.5% (12)**	9.1% (2)	0.0% (0)	0.0% (0)	4.27	22
I feel like I have a lot of problems	9.1% (2)	**45.5% (10)**	40.9% (9)	4.5% (1)	0.0% (0)	3.59	22
I feel like breaking things	22.7% (5)	**36.4% (8)**	**36.4% (8)**	4.5% (1)	0.0% (0)	3.77	22
I feel people hate me includes I feel that my life will never get any better I feel that nobody cares about me	22.7% (5)	**63.6% (14)**	13.6% (3)	0.0% (0)	0.0% (0)	4.09	22
I feel I have let myself or other people down.	4.5% (1)	**72.7% (16)**	13.6% (3)	9.1% (2)	0.0% (0)	3.73	22
I feel like doing something that will get me into trouble	18.2% (4)	27.3% (6)	**50.0% (11)**	4.5% (1)	0.0% (0)	3.59	22
I feel more sexy than usual	9.1% (2)	31.8% (7)	**45.5% (10)**	13.6% (3)	0.0% (0)	3.36	22

I have trouble concentrating includes I lose my concentration	4.5% (1)	**72.7% (16)**	13.6% (3)	9.1% (2)	0.0% (0)	3.73	22
I have been drinking and/or taking drugs includes I am getting drunk more than usual I drink to cheer myself up.	36.4% (8)	**45.5% (10)**	18.2% (4)	0.0% (0)	0.0% (0)	4.18	22
	answered question						**22**
	skipped question						**0**

FIG: Coping strategies

	Strongly agree this activity promotes mental well being	**Agree**	**Neither agree or disagree**	**Disagree**	**Strongly disagree this activity promotes mental well being**	**Rating Average**	**Response Count**
Talk to someone close to me includes ring someone I know to talk to	**54.5% (12)**	45.5% (10)	0.0% (0)	0.0% (0)	0.0% (0)	4.55	22
Tell and remind myself how well I coped before in similar situations	45.5% (10)	**50.0% (11)**	4.5% (1)	0.0% (0)	0.0% (0)	4.41	22
Looking at a photo album Looking at pictures of happy times	4.5% (1)	**68.2% (15)**	27.3% (6)	0.0% (0)	0.0% (0)	3.77	22
Do exercises. This includes sports and	40.9% (9)	**54.5%**	4.5% (1)	0.0% (0)	0.0% (0)	4.36	22

activities such as walking		**(12)**					
Do relaxation exercises includes take deep breathes Relax and rest use a stress ball, breathing exercises, aromatherapy or scented candles, get some fresh air	31.8% (7)	**50.0% (11)**	18.2% (4)	0.0% (0)	0.0% (0)	4.14	22
Use a support group Speak to some one outside your team you trust. This includes talk to family and friends, someone who can give you time Ring someone for help on a helpline e.g. Samaritans	45.5% (10)	**50.0% (11)**	4.5% (1)	0.0% (0)	0.0% (0)	4.41	22
Go for a walk	13.6% (3)	**68.2% (15)**	18.2% (4)	0.0% (0)	0.0% (0)	3.95	22
Visit a friend or family	13.6% (3)	**72.7% (16)**	13.6% (3)	0.0% (0)	0.0% (0)	4.00	22
Listen to music	27.3% (6)	**54.5% (12)**	18.2% (4)	0.0% (0)	0.0% (0)	4.09	22
Get away from what is upsetting me	13.6% (3)	**59.1% (13)**	27.3% (6)	0.0% (0)	0.0% (0)	3.86	22
Write about what upsets me includes write in my diary how I will cope	9.1% (2)	**63.6% (14)**	27.3% (6)	0.0% (0)	0.0% (0)	3.82	22
Tell myself I will be OK	18.2% (4)	**59.1% (13)**	22.7% (5)	0.0% (0)	0.0% (0)	3.95	22
Going to the gym	9.1% (2)	**63.6% (14)**	27.3% (6)	0.0% (0)	0.0% (0)	3.82	22
Try not to make things worse by arguing	0.0% (0)	**59.1% (13)**	36.4% (8)	0.0% (0)	4.5% (1)	3.50	22
Go to my room	4.5% (1)	31.8% (7)	**59.1% (13)**	0.0% (0)	4.5% (1)	3.32	22

Tidy my room.	0.0% (0)	36.4% (8)	**63.6% (14)**	0.0% (0)	0.0% (0)	3.36	22
Go to the library includes read a book draw a picture about how I am feeling Think about something happy	4.5% (1)	**45.5% (10)**	**45.5% (10)**	4.5% (1)	0.0% (0)	3.50	22
Watching a favourite DVD Watch TV or DVD	4.5% (1)	**68.2% (15)**	27.3% (6)	0.0% (0)	0.0% (0)	3.77	22
Play a tape of a friendly voice (someone you know)	4.5% (1)	**68.2% (15)**	22.7% (5)	4.5% (1)	0.0% (0)	3.73	22
Arranging to go out with a friend Socialise, includes day trips, pub, disco and clubs or inviting a friend for dinner	36.4% (8)	**54.5% (12)**	9.1% (2)	0.0% (0)	0.0% (0)	4.27	22
Gardening	9.1% (2)	**45.5% (10)**	**45.5% (10)**	0.0% (0)	0.0% (0)	3.64	22
Stop taking alcohol	18.2% (4)	**54.5% (12)**	27.3% (6)	0.0% (0)	0.0% (0)	3.91	22
Speak or get help from someone in your team includes having a check up, ask about medication, talk to key worker, see a counsellor have a check up, call for CPN	40.9% (9)	**59.1% (13)**	0.0% (0)	0.0% (0)	0.0% (0)	4.41	22
Keep busy. This includes job hunting, go to classes, go shopping tidy up	13.6% (3)	**72.7% (16)**	13.6% (3)	0.0% (0)	0.0% (0)	4.00	22
Use a comforter such as a teddy	4.5% (1)	27.3% (6)	**63.6% (14)**	4.5% (1)	0.0% (0)	3.32	22
Do hobbies. This includes stamp	22.7% (5)	**59.1% (13)**	18.2% (4)	0.0% (0)	0.0% (0)	4.05	22

collecting; puzzles play games use the computer							
	answered question						**22**
	skipped question						**0**

Both the self report statements and the coping strategies were ranked in order using a rating average.

FIG: Self report statements

		Rating average
1	I have thoughts that I would be better off dead includes I want to die I don't want to be alive	4.64
1	I am hearing things that are not there	4.64
3	I feel like cutting myself Includes I feel like hurting myself hurting myself in some way	4.50
4	I think people know what I am thinking includes I believe people can play with my thoughts I feel people can control me	4.45
5	I feel I cant go on	4.36
6	I feel like I am in a panic includes I feel anxious I feel anxious this includes feeling worried, I feel my heart pounding, I feel hot and cold, I feel tingly, I have the shakes	4.27
6	I find it difficult to do things includes I have stopped activities, I am losing interest in day to day life, I have stopped going out	4.27
6	I have stopped bathing and changing my clothes.	4.27
9	I am having problems with sleeping includes I have trouble with sleeping. I am having problems with sleep nightmares, waking up, getting out of bed, I am not sleeping, I feel tired	4.23
10	I have been drinking and/or taking drugs includes I am getting drunk more than usual I drink to cheer myself up.	4.18
11	I don't feel like eating I lose my appetite	4.05

FIG: Coping strategies

		Rating average
1	Talk to someone close to me includes ring someone I know to talk to	4.55
2	Tell and remind myself how well I coped before in similar situations	4.41
2	Use a support group Speak to some one outside your team you trust. This includes talk to family and friends, someone who can give you time Ring someone for help on a helpline e.g. Samaritans	4.41
2	Speak or get help from someone in your team includes having a check up, ask about medication, talk to key worker, see a counsellor have a check up, call for CPN	4.41
5	Do exercises. This includes sports and activities such as walking	4.36
6	Arranging to go out with a friend Socialise, includes day trips, pub, disco and clubs or inviting a friend for dinner	4.27
7	Do relaxation exercises includes take deep breathes Relax and rest use a stress ball, breathing exercises, aromatherapy or scented candles, get some fresh air	4.14
8	Listen to music	4.09
9	Do hobbies. This includes stamp collecting; puzzles play games use the computer	4.05
10	Keep busy. This includes job hunting, go to classes, go shopping tidy up	4.00
10	Visit a friend or family	4.00

Round 3

The third round consisted of the focus group given a prototype 'SAINT', outlining the categories and examples chosen from rounds 1 and 2 and instructions for use. The user group was asked for final comments regarding the set out and ease of use and of the prototype and for final comments on how to make it as user friendly as possible. The final list comprised of 10 statements, each with up to 5 examples, for both the assessment of mental distress and coping strategies. The final task of the expert group was to vote to keep the top 3 or 4.

TABLE Final Evaluations of categories and examples

	KEEP	DELETE	Response Count
NEGATIVE THOUGHTS _- I AM HAVING BAD THOUGHTS	**92.3% (12)**	7.7% (1)	13

	KEEP	DELETE	Response Count
I feel like I can't go on	**76.9% (10)**	23.1% (3)	13
I feel like hurting myself	**100.0% (12)**	0.0% (0)	12
I don't want to be alive	**100.0% (12)**	0.0% (0)	12
I don't want to be here	33.3% (5)	**66.7% (10)**	15
People would be better off without me	**75.0% (9)**	25.0% (3)	12
PSYCHOTIC SYMPTOMS - I AM NOT FEELING MYSELF	**91.7% (11)**	8.3% (1)	12
I am hearing things that are not there	**100.0% (12)**	0.0% (0)	12
I feel people know what I am thinking	**84.6% (11)**	15.4% (2)	13
I feel people can control me	**66.7% (8)**	33.3% (4)	12
I feel people can play with my thoughts	**91.7% (11)**	8.3% (1)	12
I feel strange	35.7% (5)	**64.3% (9)**	14
ANXIETY - I FEEL IN A PANIC	**100.0% (12)**	0.0% (0)	12
I feel my heart pounding	**100.0% (12)**	0.0% (0)	12
I feel hot and cold	**57.1% (8)**	42.9% (6)	14
I feel tingly	46.2% (6)	**53.8% (7)**	13
I have the shakes	**83.3% (10)**	16.7% (2)	12
I am sweating	**66.7% (8)**	33.3% (4)	12
MOTIVATION - I FIND IT DIFFICULT TO DO THINGS	**91.7% (11)**	8.3% (1)	12
I am losing interest in things	**92.3% (12)**	7.7% (1)	13
I can't concentrate	**91.7% (11)**	8.3% (1)	12
I can't be bothered to change my clothes	**91.7% (11)**	8.3% (1)	12
I have stopped activities	**83.3% (10)**	16.7% (2)	12
I want people to leave me alone	42.9% (6)	**57.1% (8)**	14
SLEEP - I HAVE PROBLEMS SLEEPING	**100.0% (12)**	0.0% (0)	12
I have trouble getting off to sleep	**100.0% (12)**	0.0% (0)	12
I have trouble waking up	**75.0% (9)**	25.0% (3)	12

	KEEP	DELETE	Response Count
I keep getting up during the night	**76.9% (10)**	23.1% (3)	13
I am having nightmares	**50.0% (7)**	**50.0% (7)**	14
I feel tired all the time	**83.3% (10)**	16.7% (2)	12
FEELING DOWN - I FEEL DOWN TODAY	**100.0% (12)**	0.0% (0)	12
I feel sad	**100.0% (12)**	0.0% (0)	12
I feel worried	**100.0% (12)**	0.0% (0)	12
I feel tense	**61.5% (8)**	38.5% (5)	13
I feel stressed	**83.3% (10)**	16.7% (2)	12
I feel uptight	46.2% (6)	**53.8% (7)**	13
NOT BEING IN CONTROL - I DONT FEEL IN CONTROL	**100.0% (12)**	0.0% (0)	12
I am worried about my temper	**91.7% (11)**	8.3% (1)	12
I am worried I will react badly to things	**53.3% (8)**	46.7% (7)	15
I feel angry	**91.7% (11)**	8.3% (1)	12
I am worried about drinking too much and/or drugs	**66.7% (8)**	33.3% (4)	12
I am worried I will explode	**75.0% (9)**	25.0% (3)	12
SELF-ESTEEM - I FEEL BAD ABOUT MYSELF	**100.0% (12)**	0.0% (0)	12
I feel people do not like me	**75.0% (9)**	25.0% (3)	12
I feel my life will not get any better	**83.3% (10)**	16.7% (2)	12
I feel everyone hates and ignores me	**84.6% (11)**	15.4% (2)	13
I keep letting people down	**91.7% (11)**	8.3% (1)	12
Nobody cares	**53.8% (7)**	46.2% (6)	13
EMOTIONS AND FEELINGS - I FEEL EMOTIONAL	**100.0% (13)**	0.0% (0)	13
My mood keeps going up and down	**100.0% (12)**	0.0% (0)	12
I feel heartbroken	**66.7% (8)**	33.3% (4)	12
I feel unwell	**61.5% (8)**	38.5% (5)	13

	KEEP	DELETE	Response Count
I am in pain	**91.7% (11)**	8.3% (1)	12
I find it hard to be sensible	42.9% (6)	**57.1% (8)**	14
OTHER ACTIVITIES OF DAILY LIVING	**100.0% (11)**	0.0% (0)	11
I am not taking good care of myself	**75.0% (9)**	25.0% (3)	12
I am not eating well	**100.0% (12)**	0.0% (0)	12
I am not washing or bathing	**100.0% (12)**	0.0% (0)	12
I am not paying my bills	40.0% (6)	**60.0% (9)**	15
I cannot concentrate on things	**91.7% (11)**	8.3% (1)	12